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Gilson et al.

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(54) **VASCULAR FILTER SYSTEM**

(71) Applicant: **Novate Medical Limited**, Dublin (IE)

(72) Inventors: **Paul Gilson**, Galway (IE); **Steven Horan**, Galway (IE); **Karl Keating**, Galway (IE); **Aidan Goggin**, Redcastle (IE)

(73) Assignee: **Novate Medical Limited**, Dublin (IE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 22 days.

(21) Appl. No.: **15/379,115**

(22) Filed: **Dec. 14, 2016**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 12/688,173, filed on Jan. 15, 2010, now abandoned.
(Continued)

(51) **Int. Cl.**
A61F 2/01 (2006.01)

(52) **U.S. Cl.**
CPC **A61F 2/01** (2013.01); **A61F 2002/011** (2013.01); **A61F 2002/016** (2013.01); **A61F 2210/0004** (2013.01); **A61F 2230/005** (2013.01); **A61F 2230/0067** (2013.01); **A61F 2230/0069** (2013.01); **A61F 2230/0091** (2013.01);

(Continued)

(58) **Field of Classification Search**
CPC **A61F 2/01**; **A61F 2/013**; **A61F 2002/011**; **A61F 2002/016**

See application file for complete search history.

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Primary Examiner — Elizabeth Houston

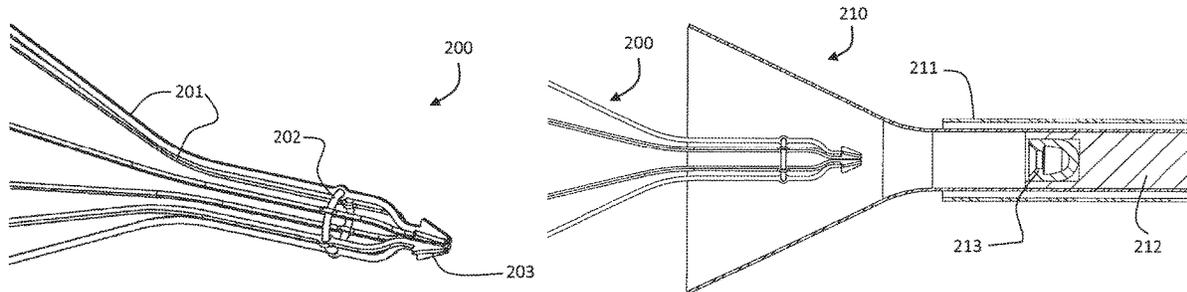
Assistant Examiner — Lindsey Bachman

(74) *Attorney, Agent, or Firm* — Seager, Tufte & Wickhem LLP

(57) **ABSTRACT**

A vascular filter system comprises a vascular filter (1), a clamp device (50), and a delivery catheter (51). The filter (1) comprises filter elements (6). When used without the clamp device (50), the filter elements (6) move from a closed state to an open state upon elapse of a predetermined period of time. In the closed state the filter elements (6) capture thrombus passing through the inferior vena cava (2). The delivery catheter (51) is employed to deliver the clamp device (50) to the filter (1) after the filter (1) has been deployed in the inferior vena cava (2). The clamp device (50) engages with the filter elements (6) of the filter (1) to clamp the filter (1) in the closed state beyond elapse of the predetermined period of time. Because of the presence of the clamp device (50), the filter elements (6) are no longer free to move from the closed state to the open state upon elapse of the predetermined period of time. In this manner the period of time in which the filter (1) captures thrombus is extended either temporarily or permanently.

13 Claims, 30 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/145,387, filed on Jan. 16, 2009.

(52) **U.S. Cl.**
CPC . A61F 2250/003 (2013.01); A61F 2250/0031 (2013.01); A61F 2250/0059 (2013.01)

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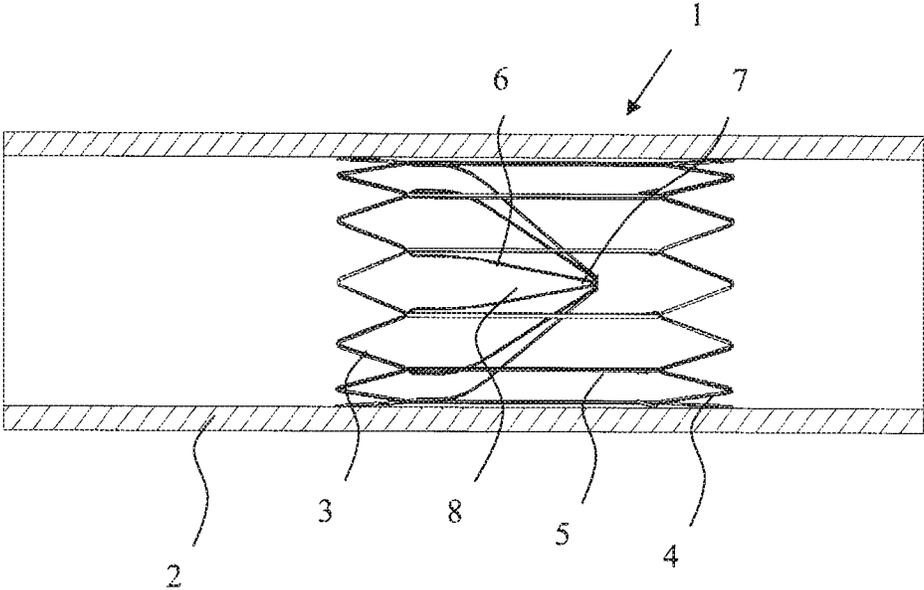


Fig. 1

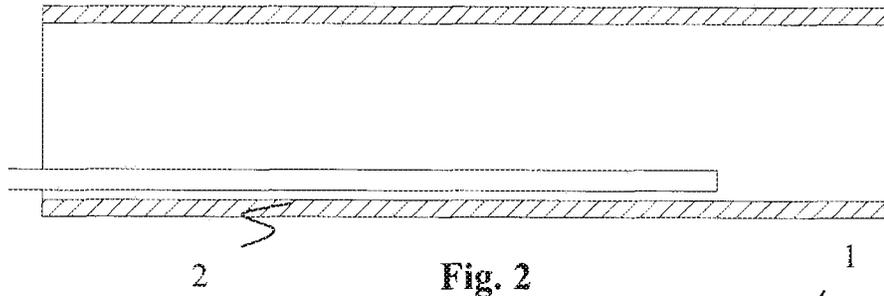


Fig. 2

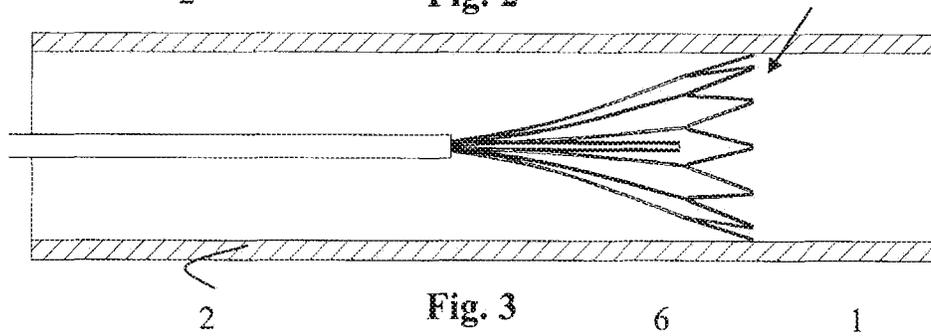


Fig. 3

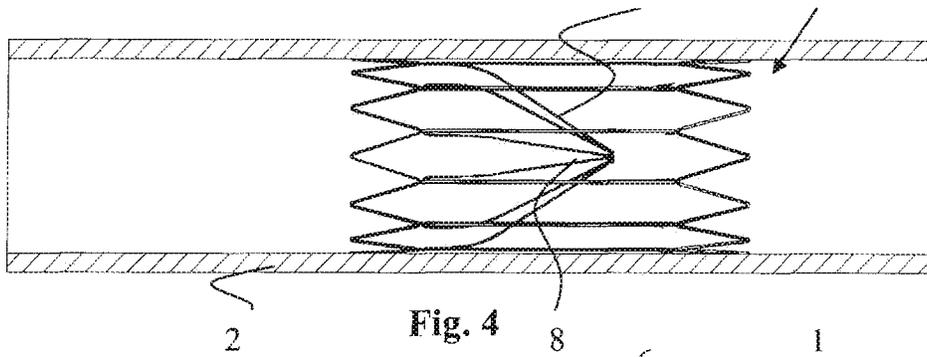


Fig. 4

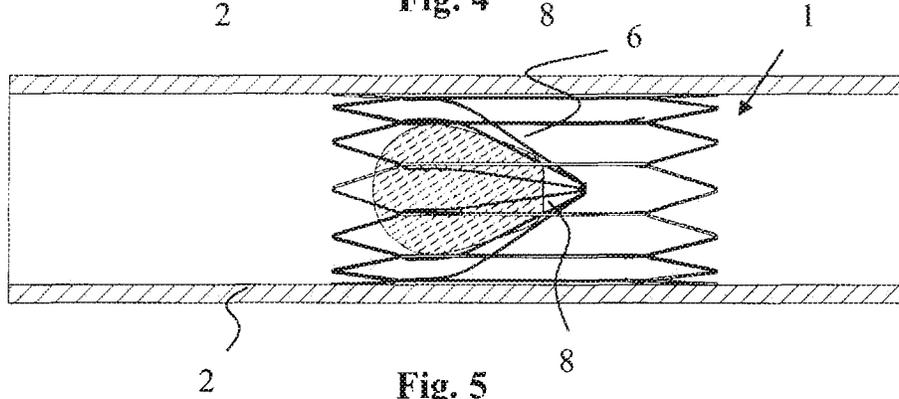


Fig. 5

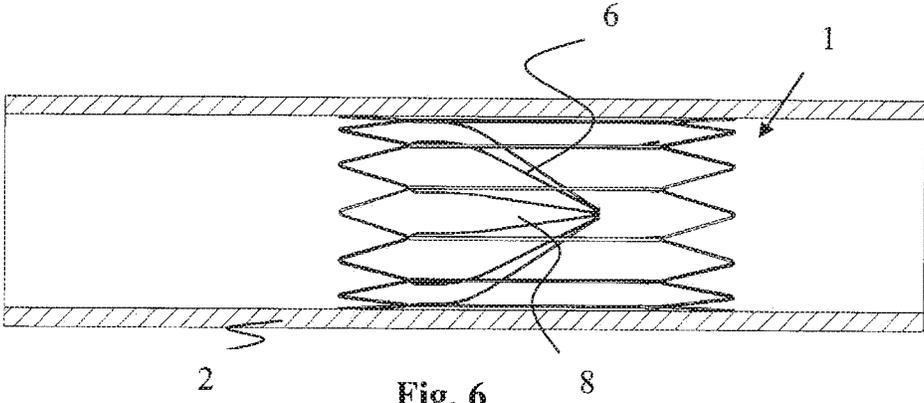


Fig. 6

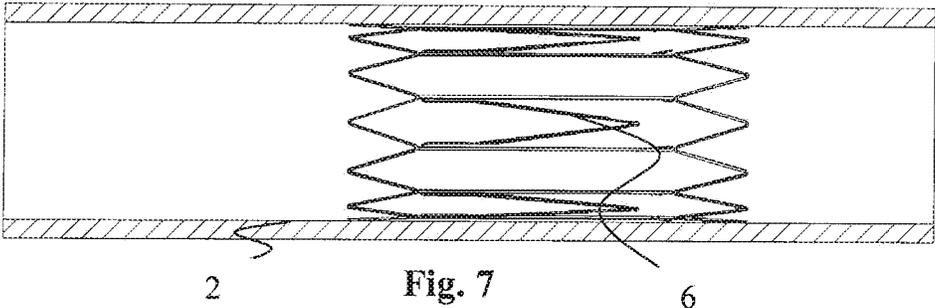


Fig. 7

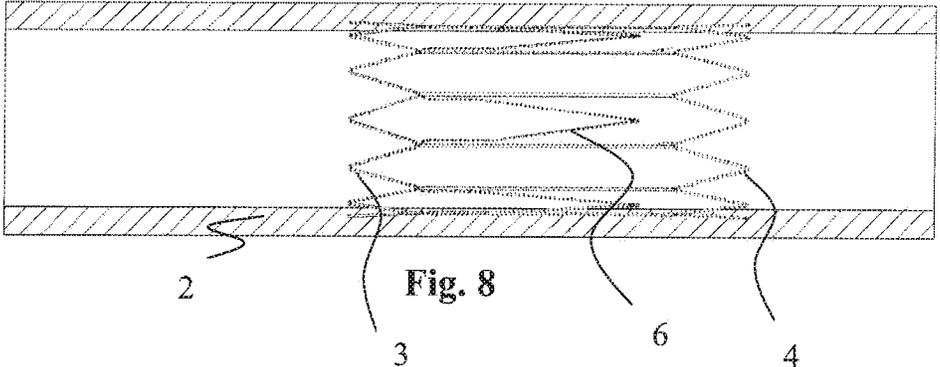


Fig. 8

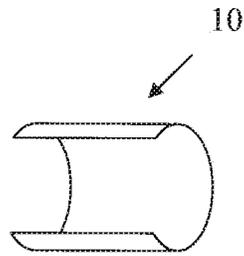


Fig. 9

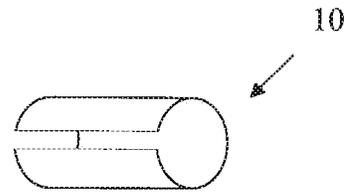


Fig. 10

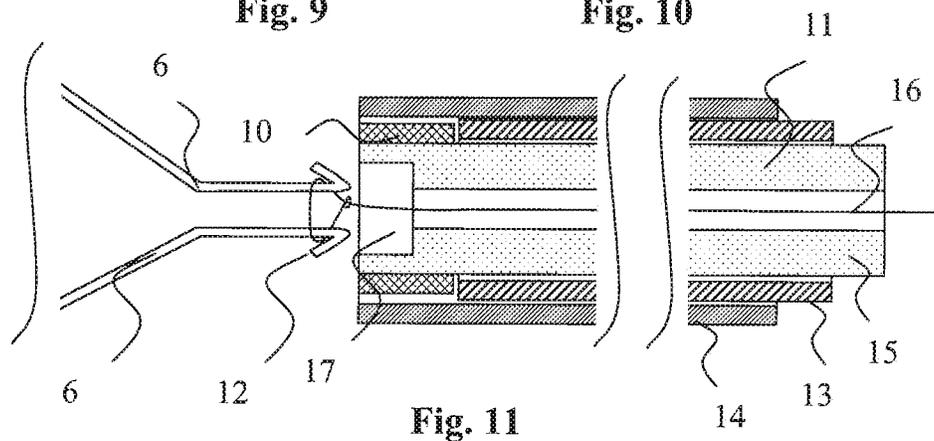


Fig. 11

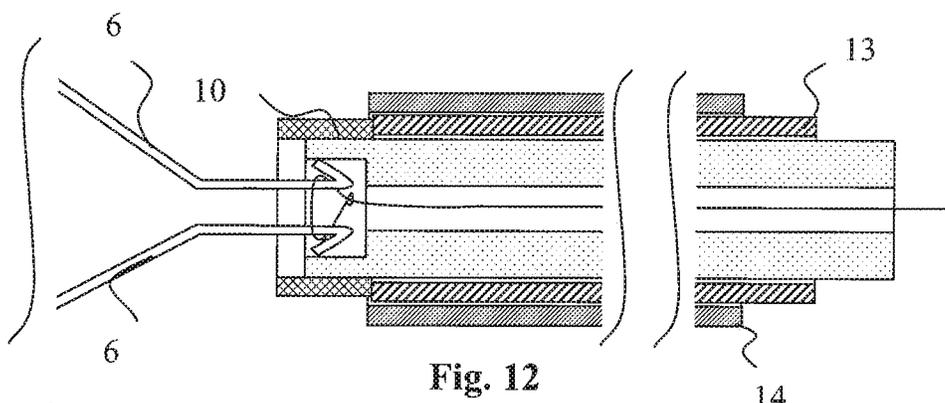


Fig. 12

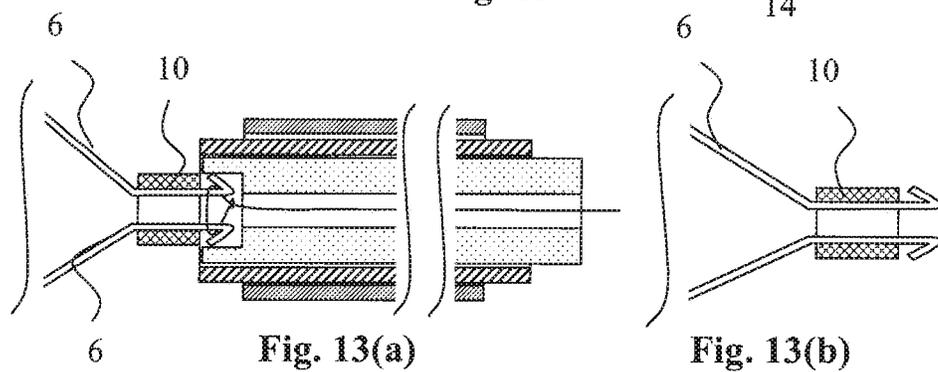


Fig. 13(a)

Fig. 13(b)

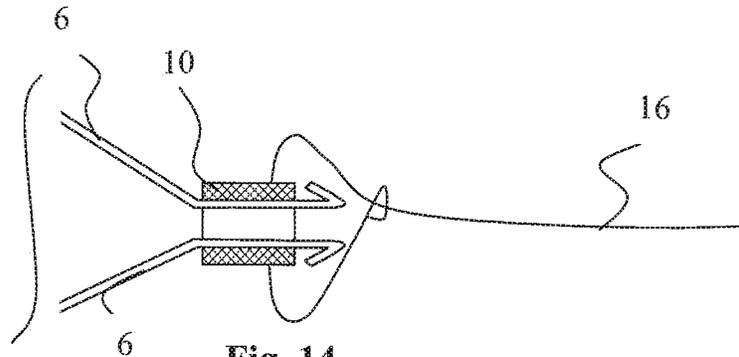


Fig. 14

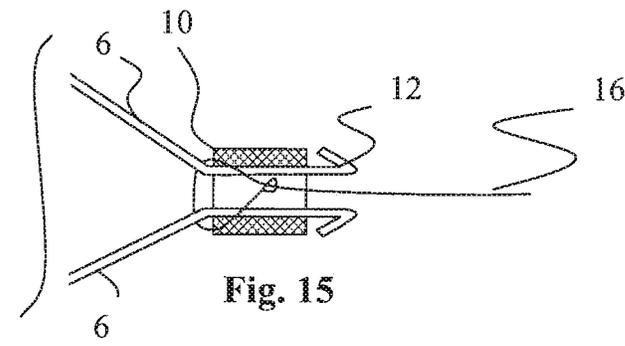


Fig. 15

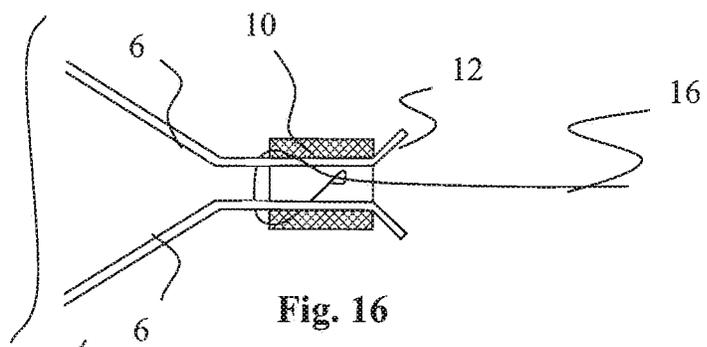


Fig. 16

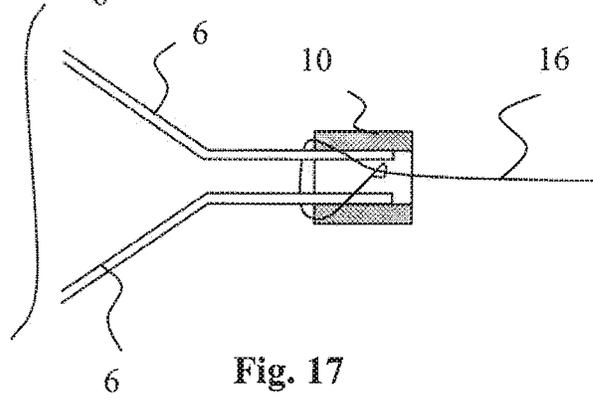


Fig. 17

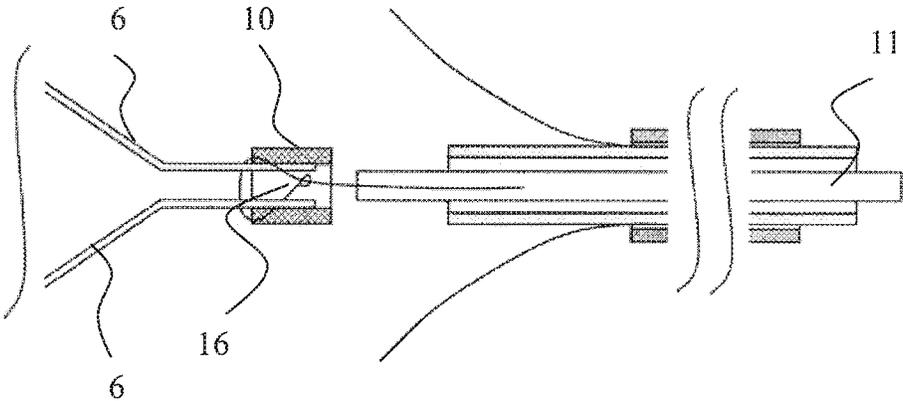


Fig. 18

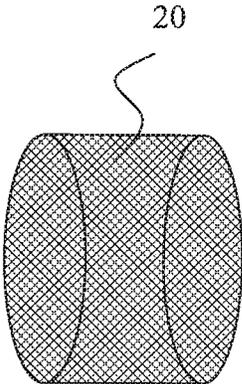


Fig. 19

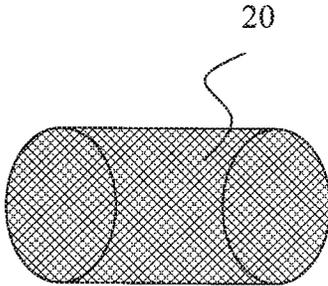


Fig. 20

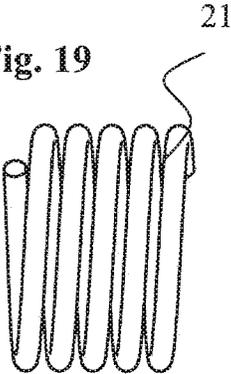


Fig. 21

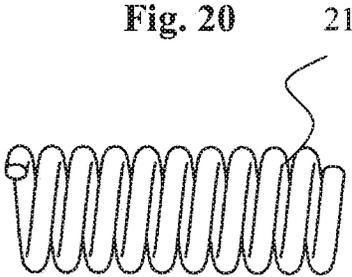


Fig. 22

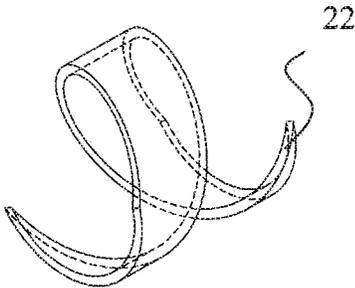


Fig. 23

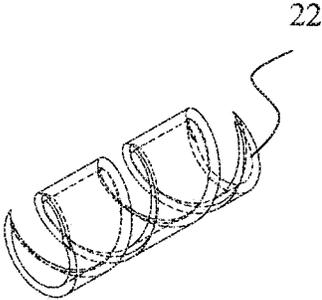
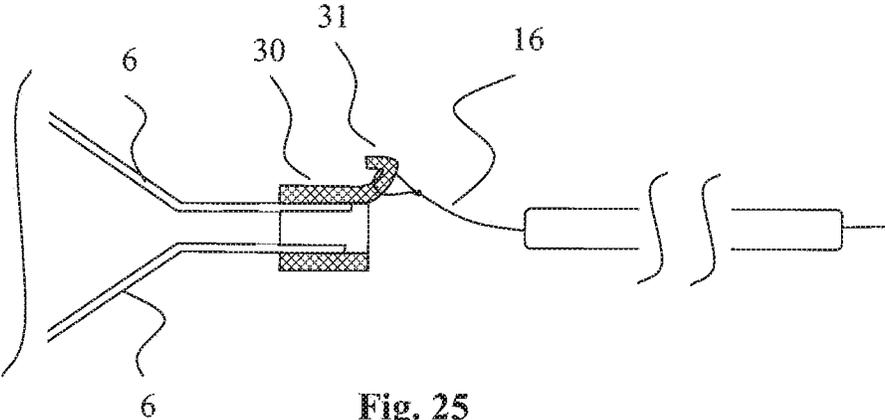
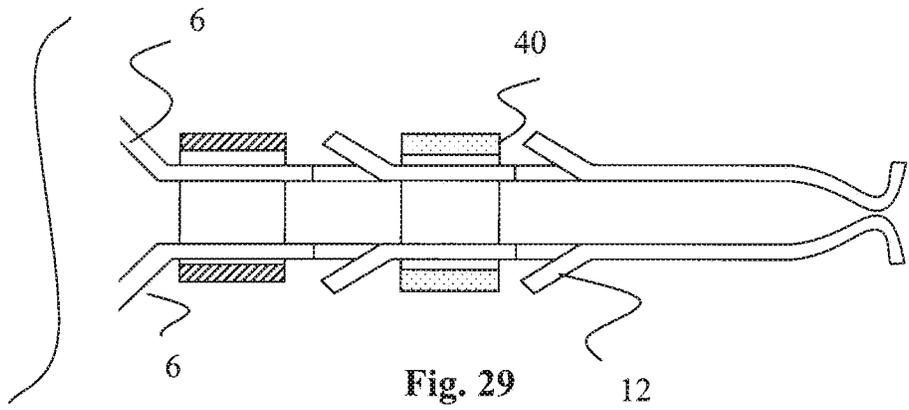
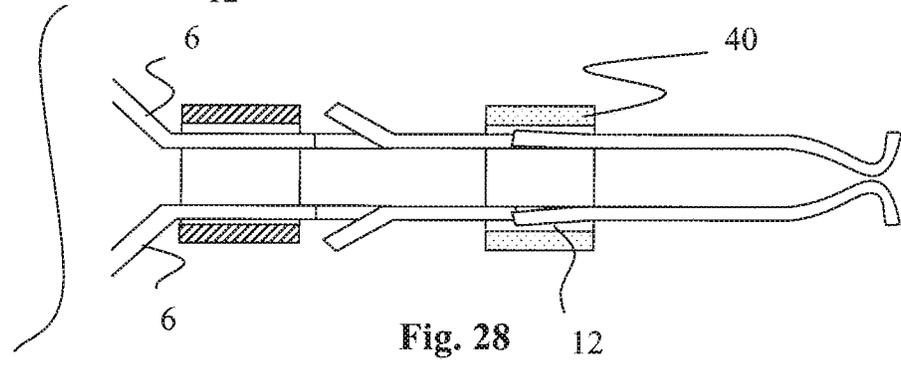
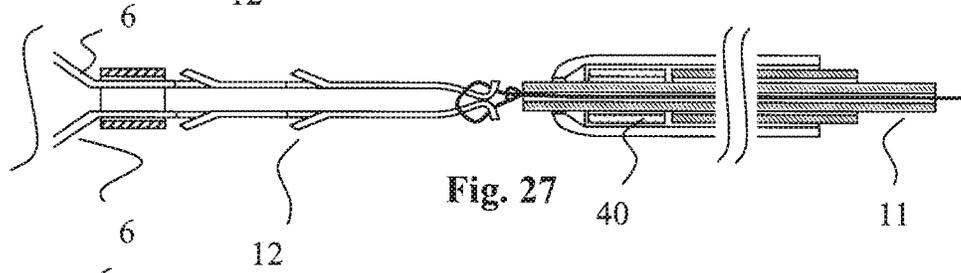
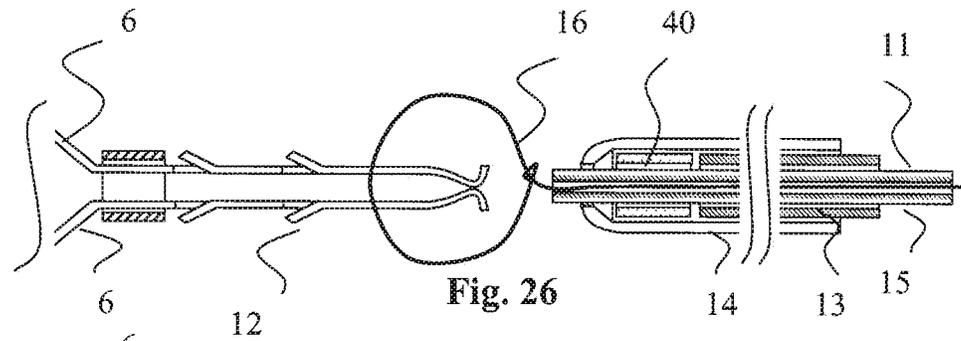
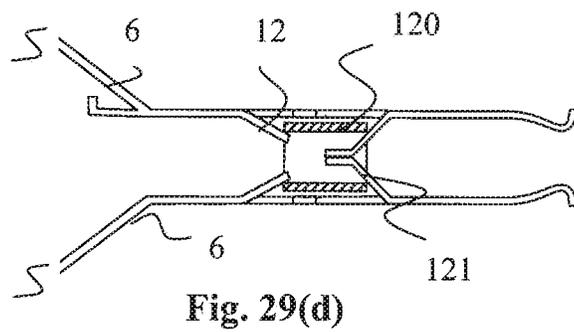
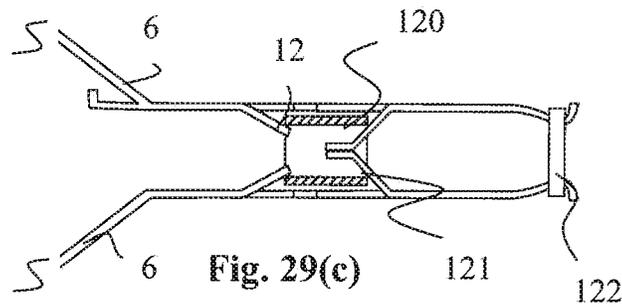
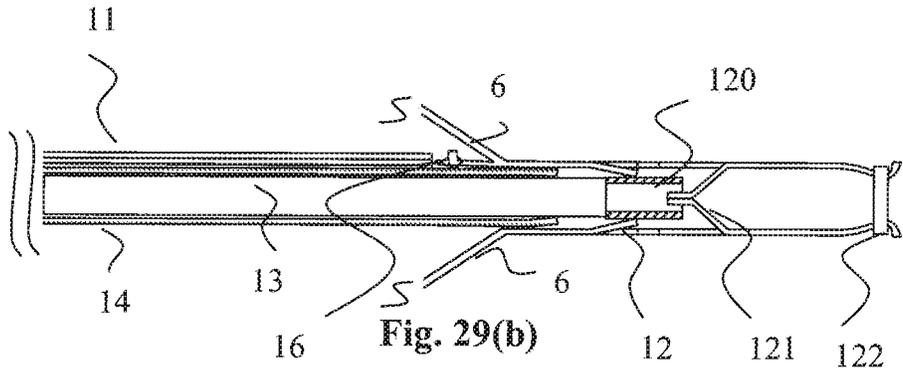
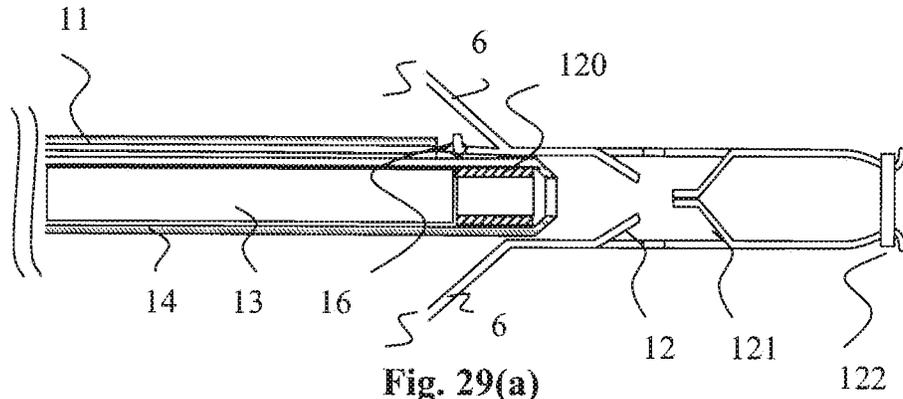


Fig. 24







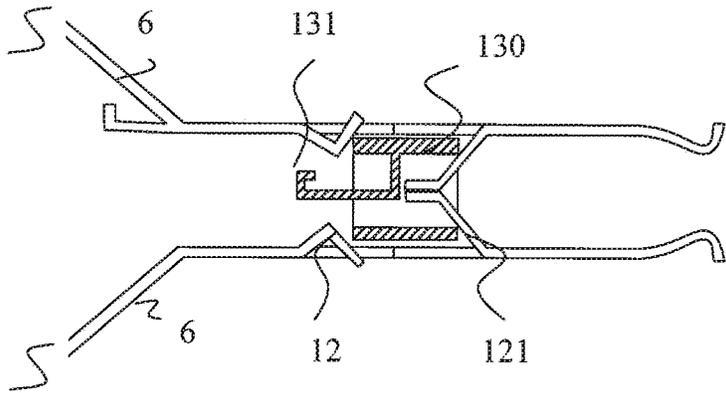


Fig. 29(e)

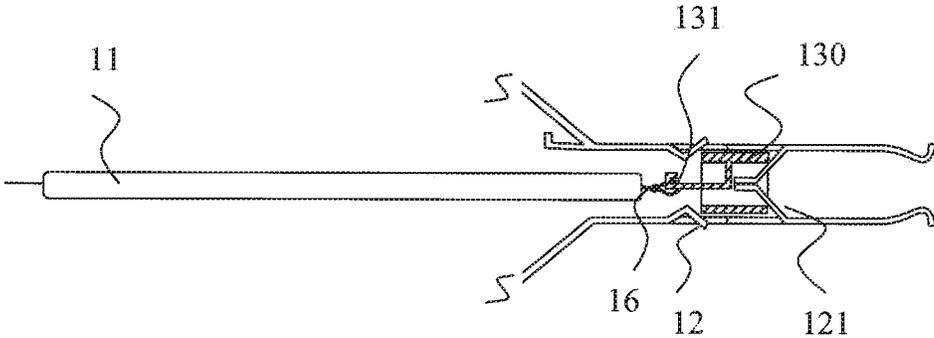


Fig. 29(f)

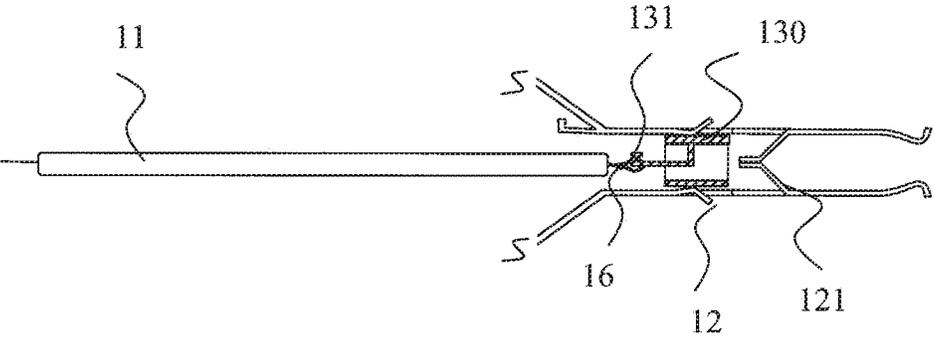


Fig. 29(g)

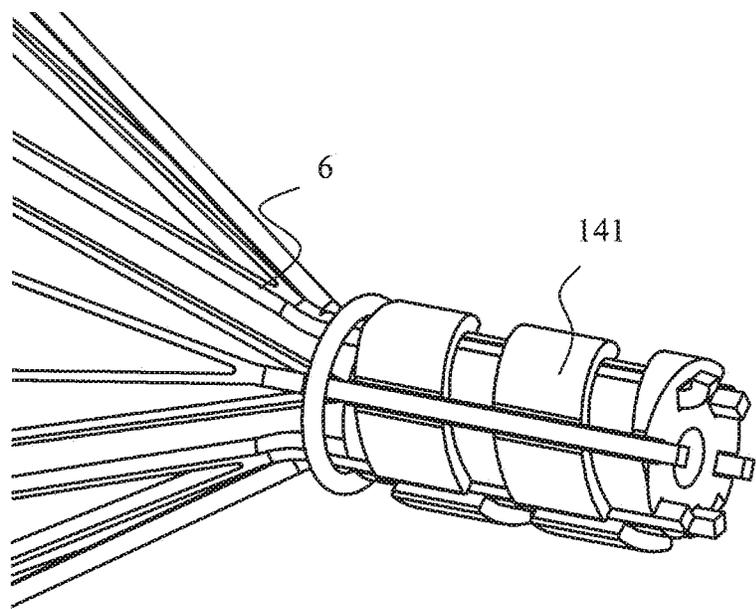


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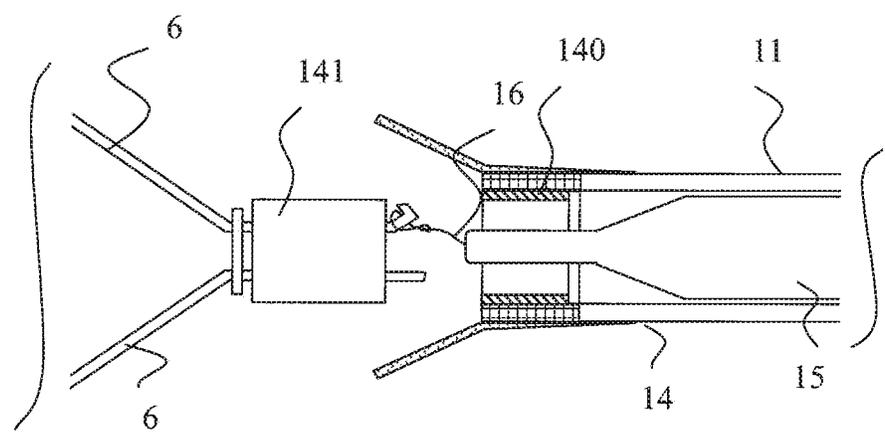


Fig. 29(i)

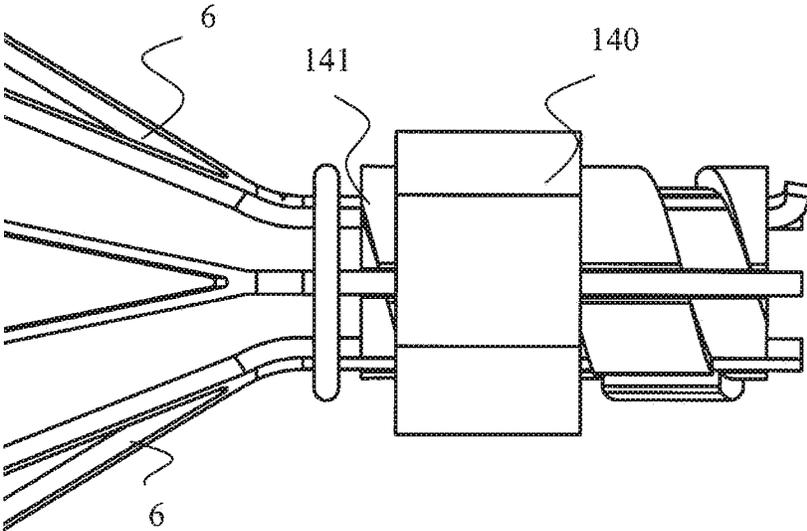


Fig. 29(j)

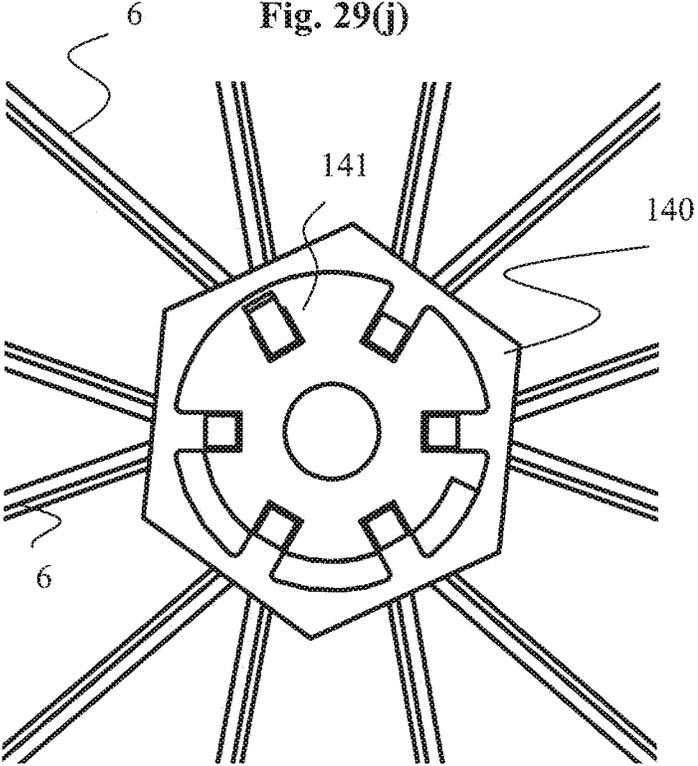


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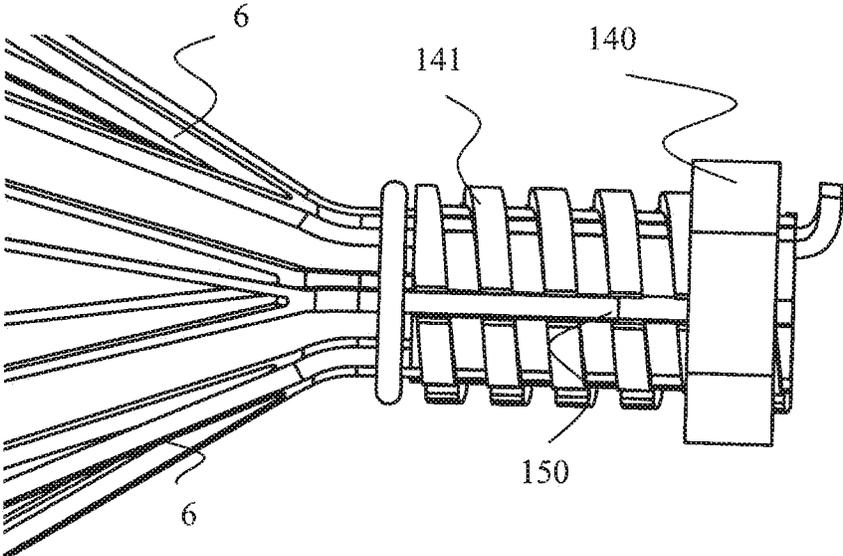


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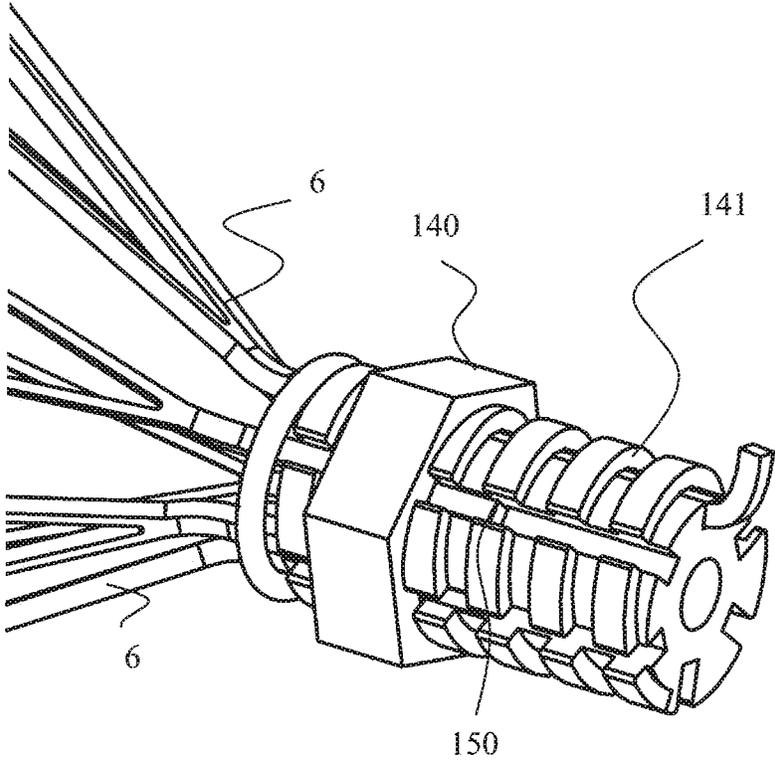
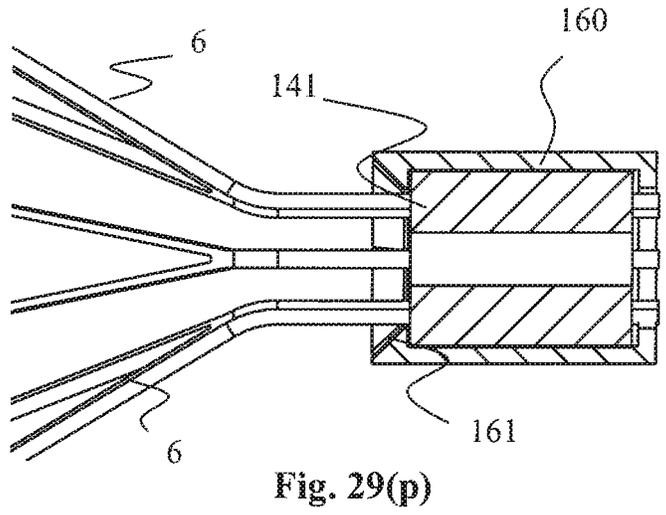
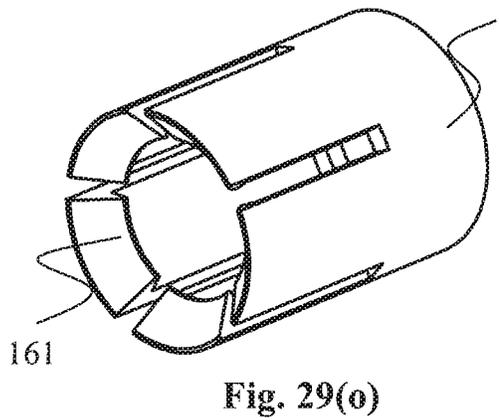
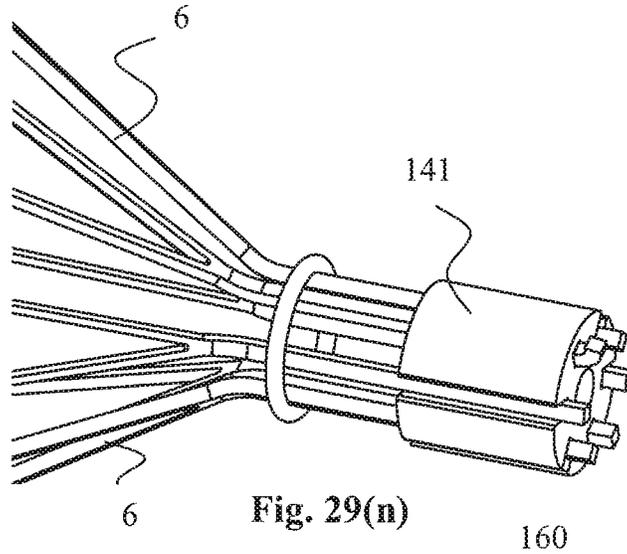
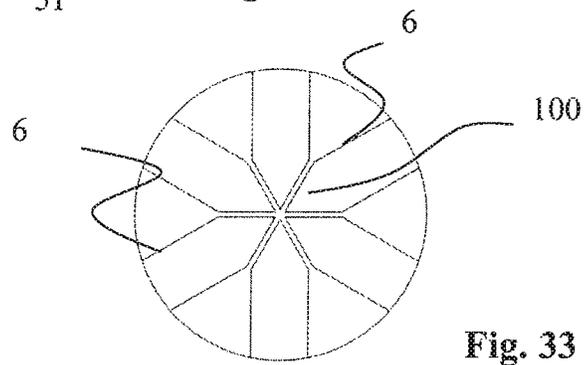
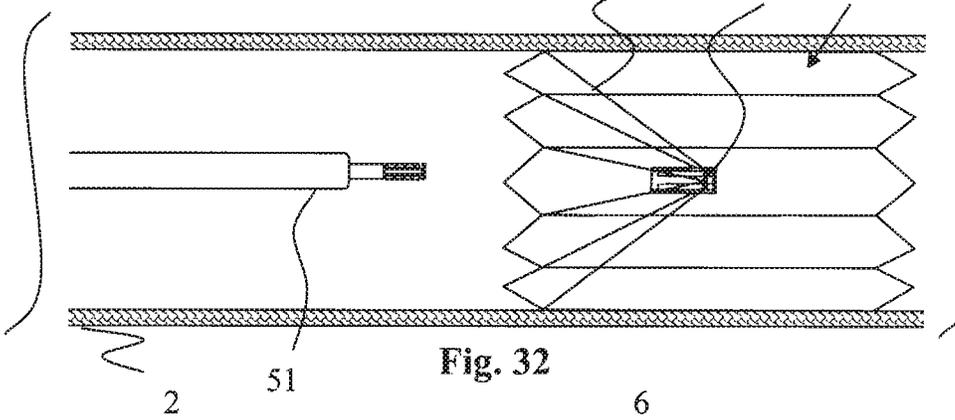
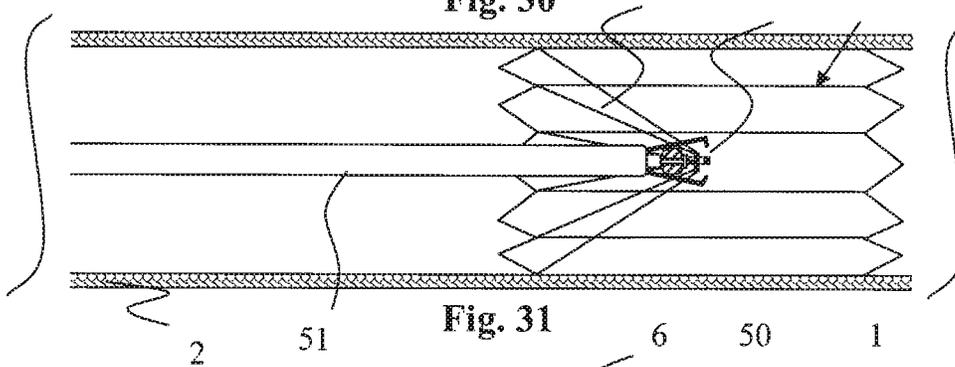
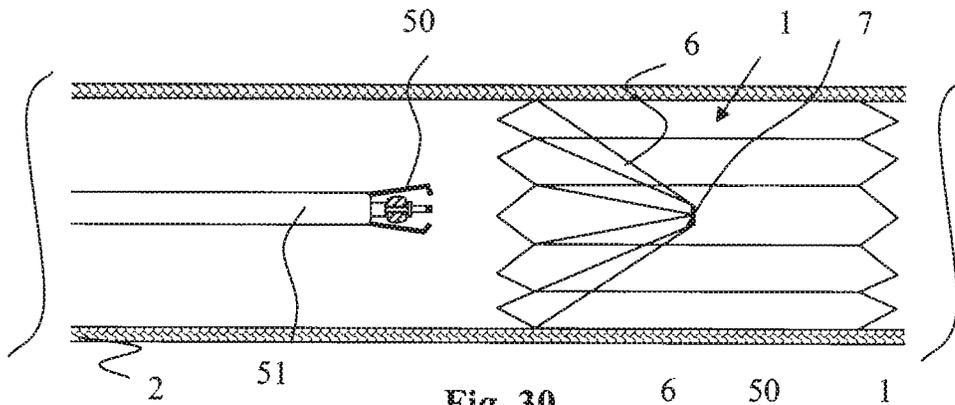


Fig. 29(m)





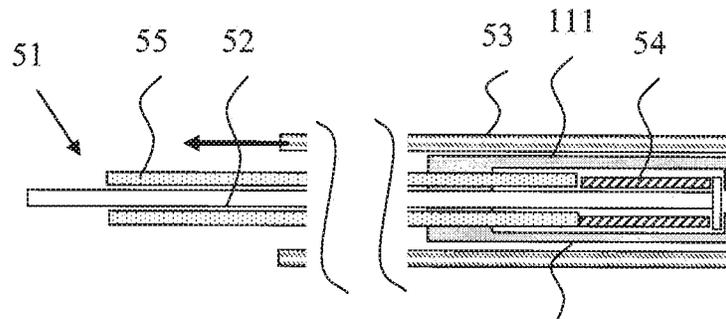


Fig. 34

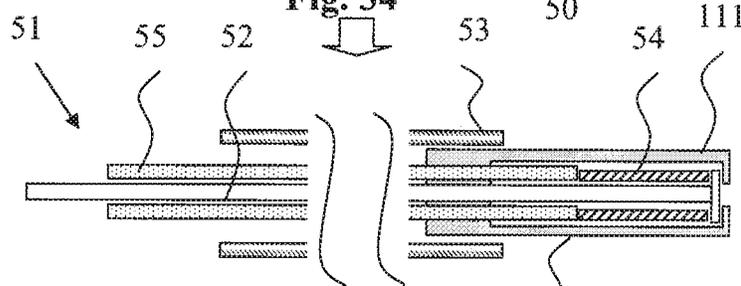


Fig. 35

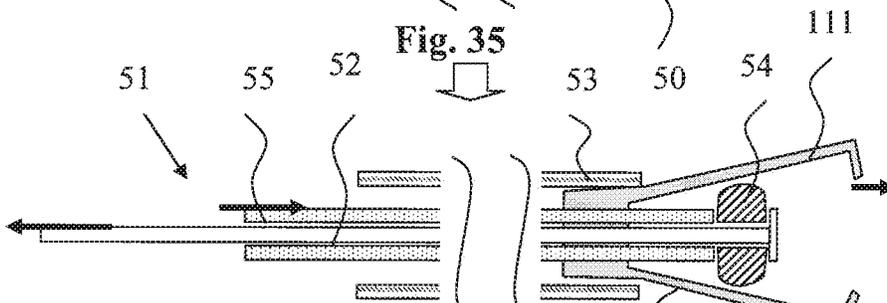


Fig. 36

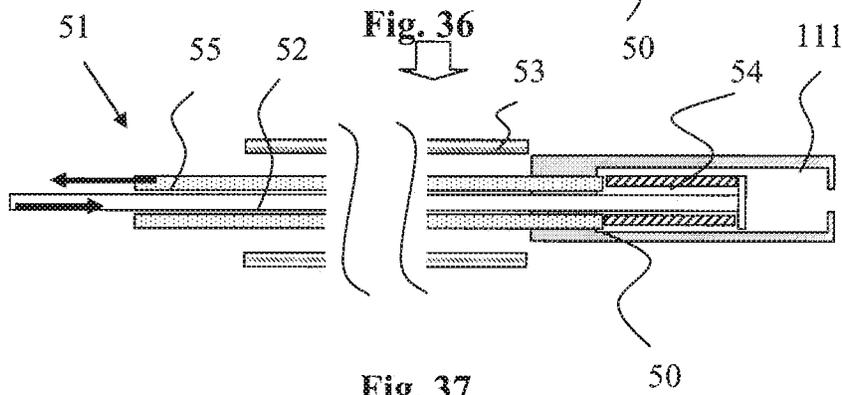


Fig. 37

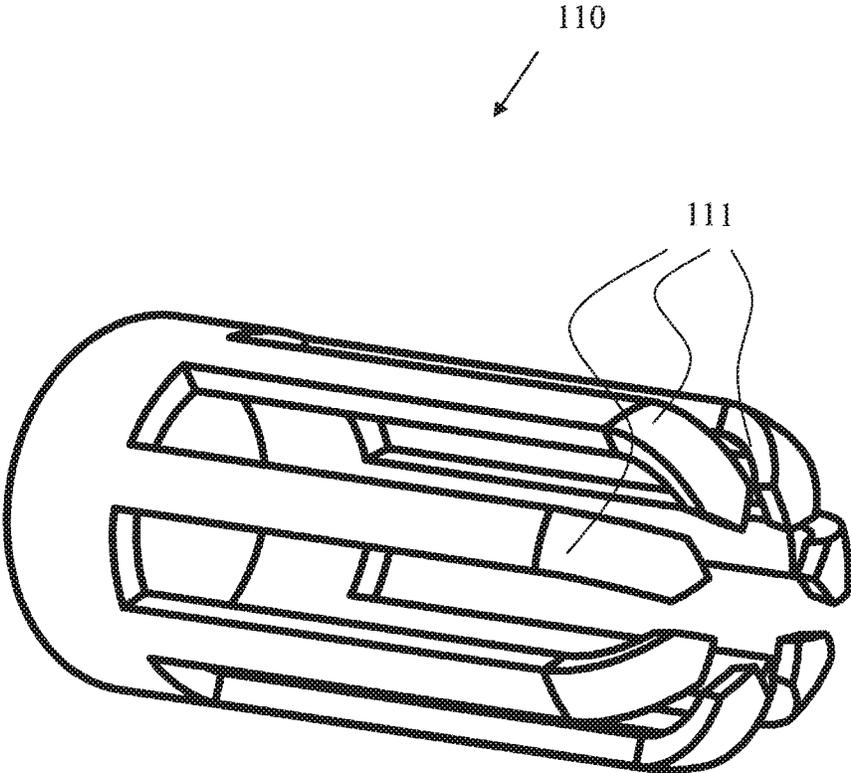


Fig. 37(a)

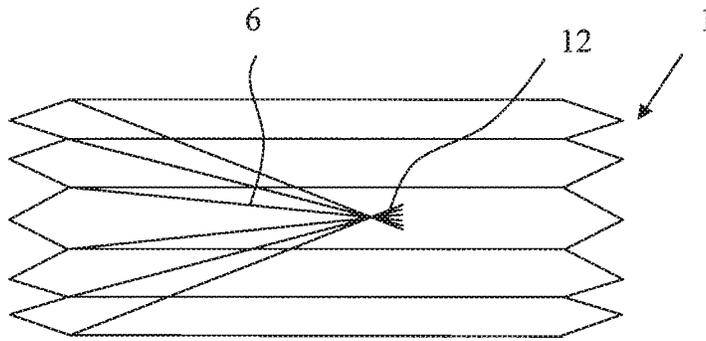


Fig. 38

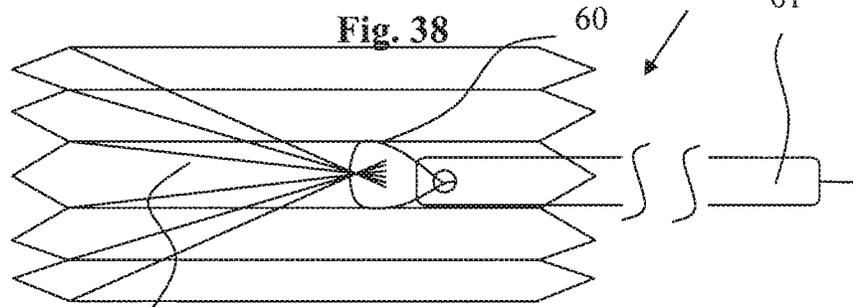


Fig. 39

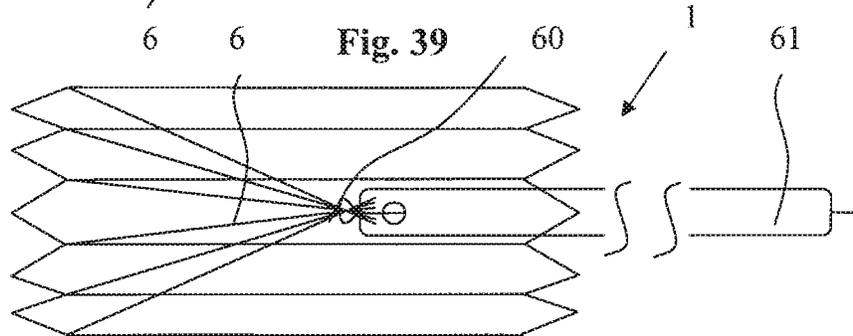


Fig. 40

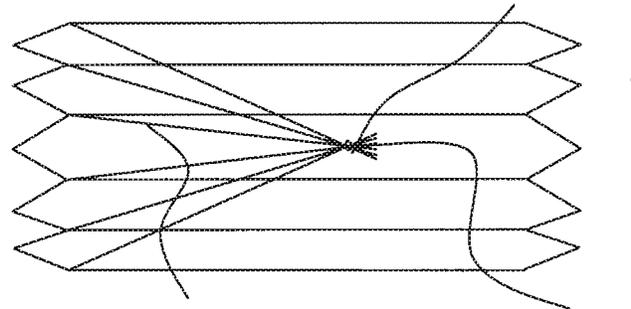


Fig. 41

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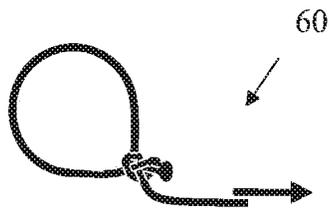


Fig. 42

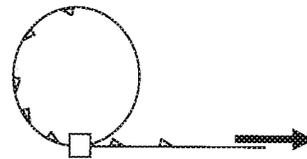


Fig. 43

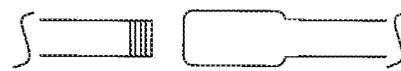
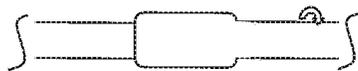


Fig. 44(a)

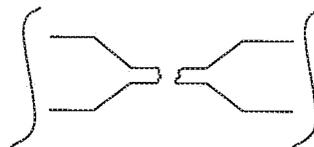
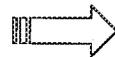
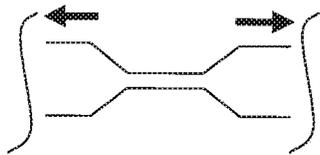


Fig. 44(b)

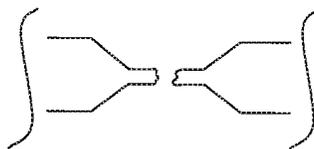
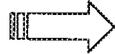
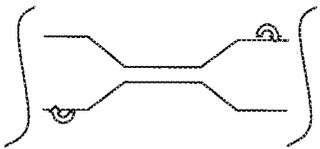


Fig. 44(c)

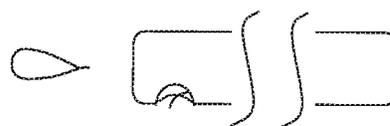
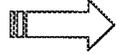
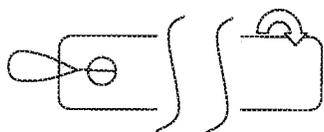


Fig. 44(d)

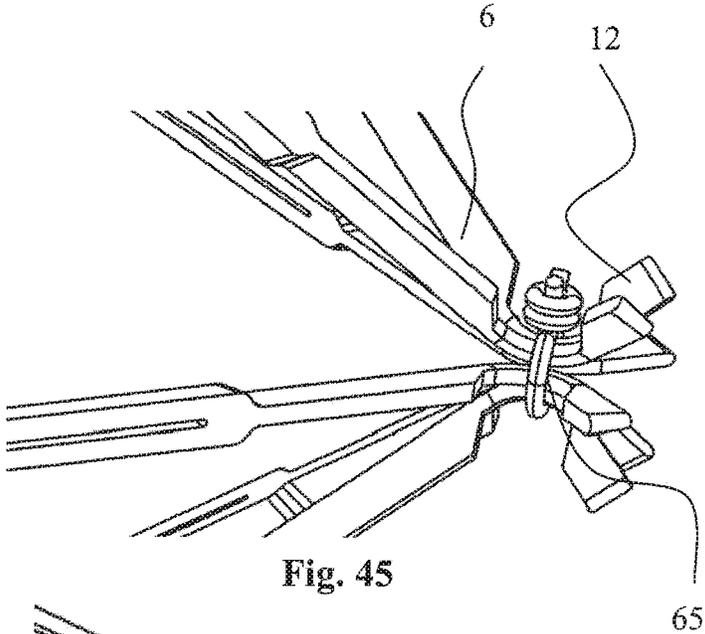


Fig. 45

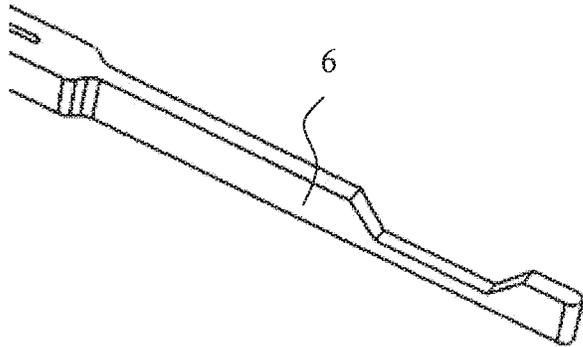


Fig. 46

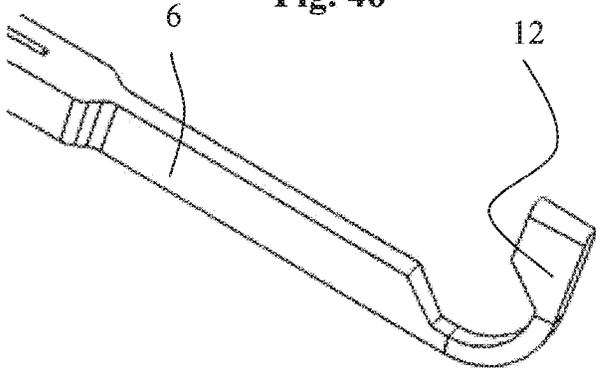


Fig. 47

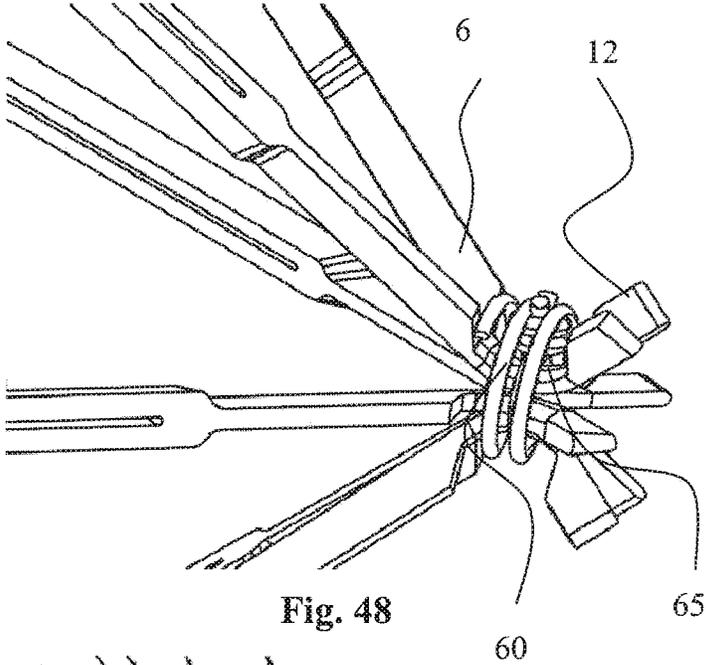


Fig. 48

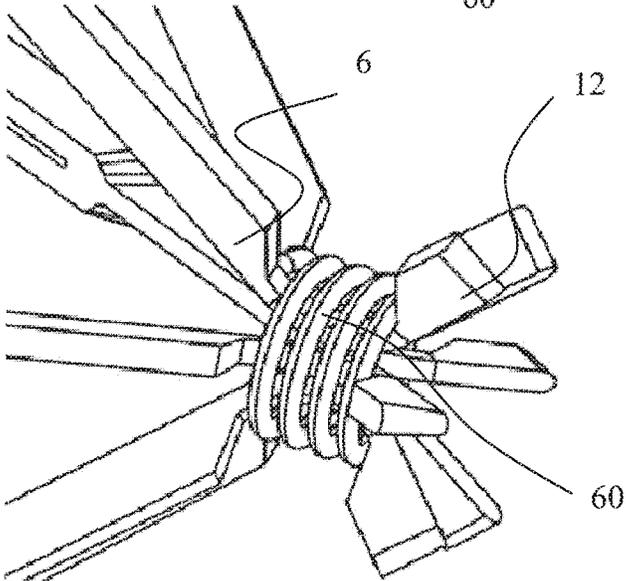


Fig. 49

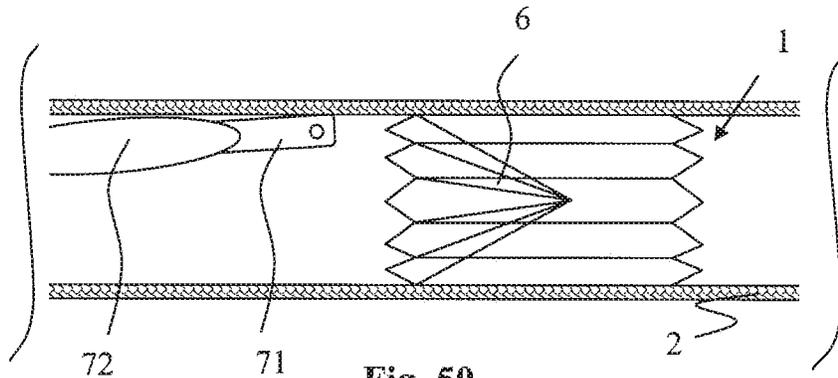


Fig. 50

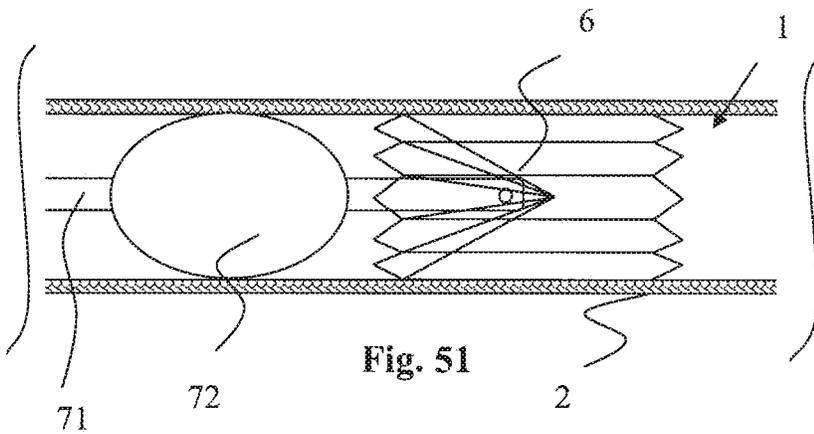


Fig. 51

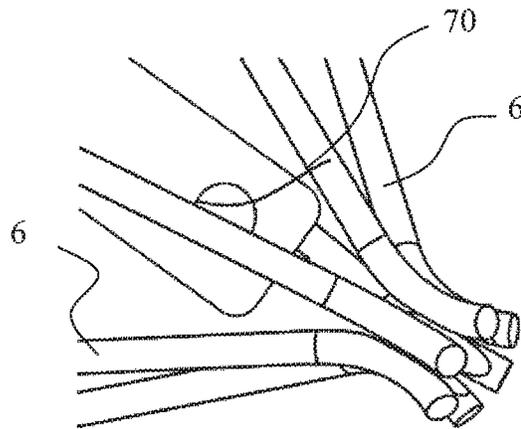


Fig. 52

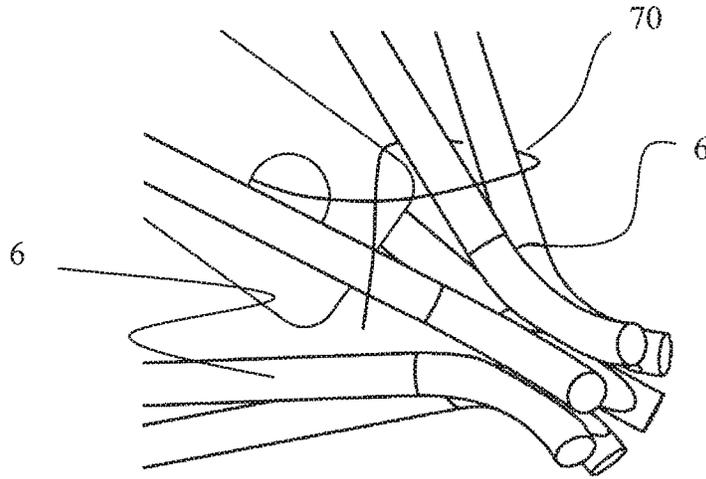


Fig. 53

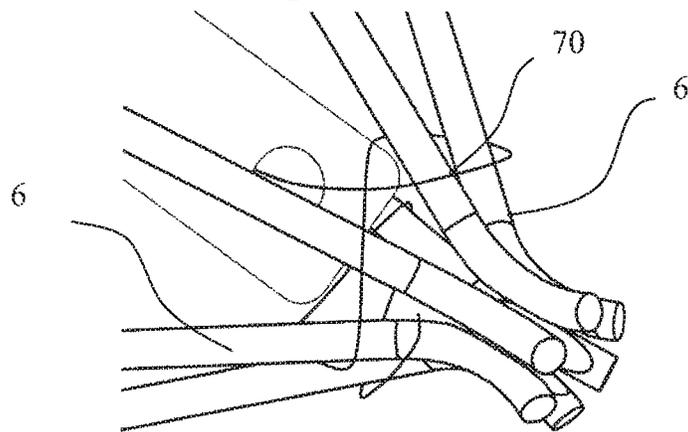


Fig. 54

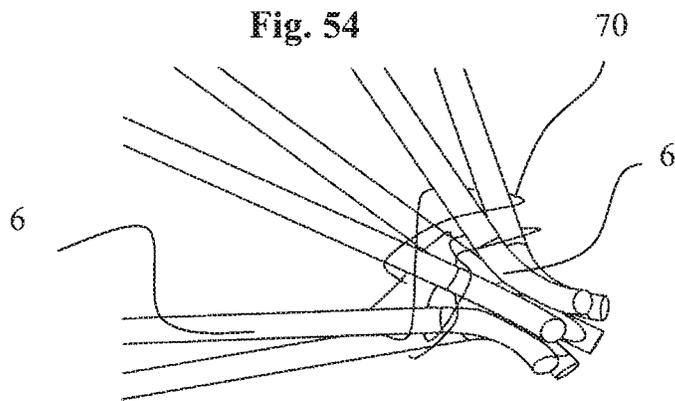
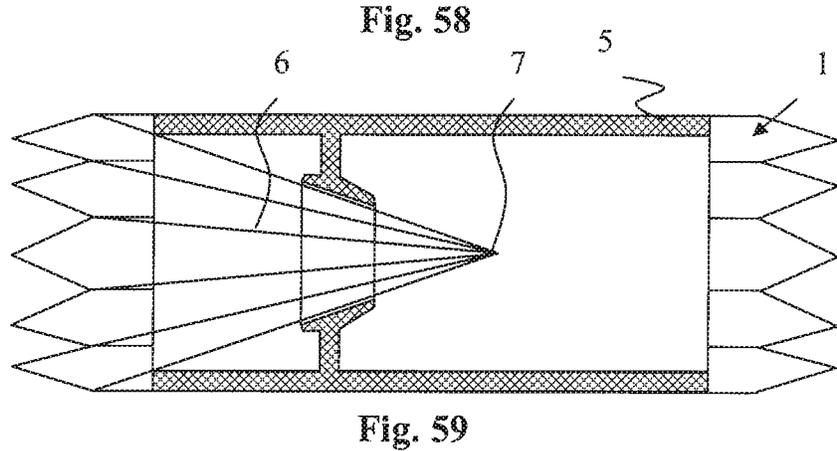
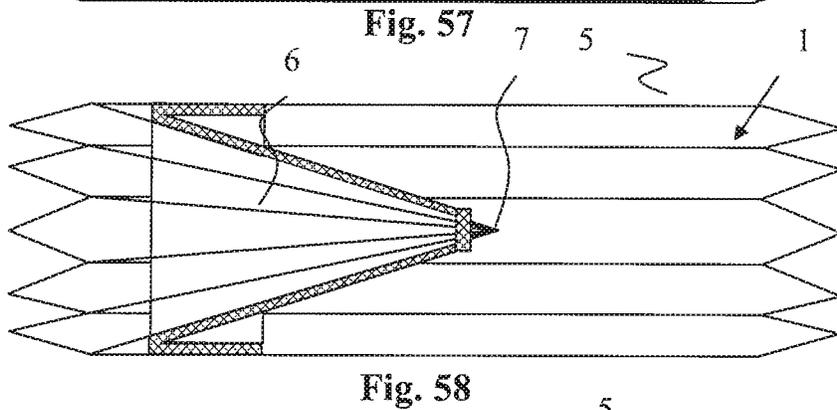
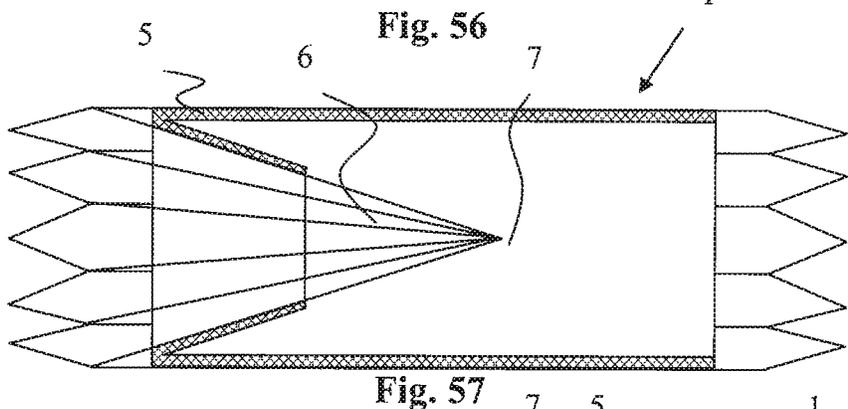
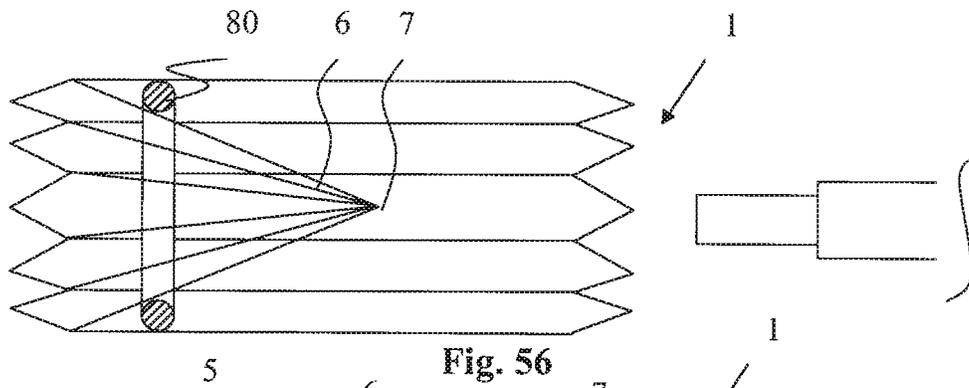
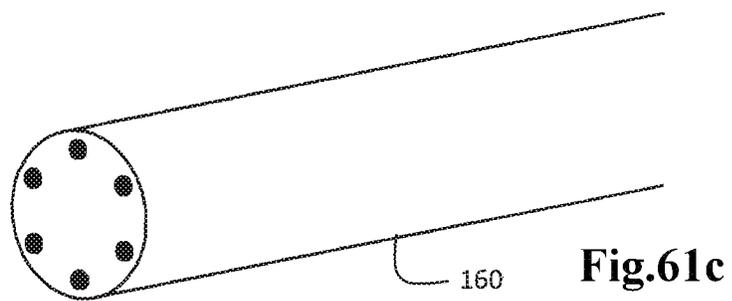
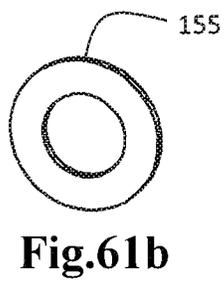
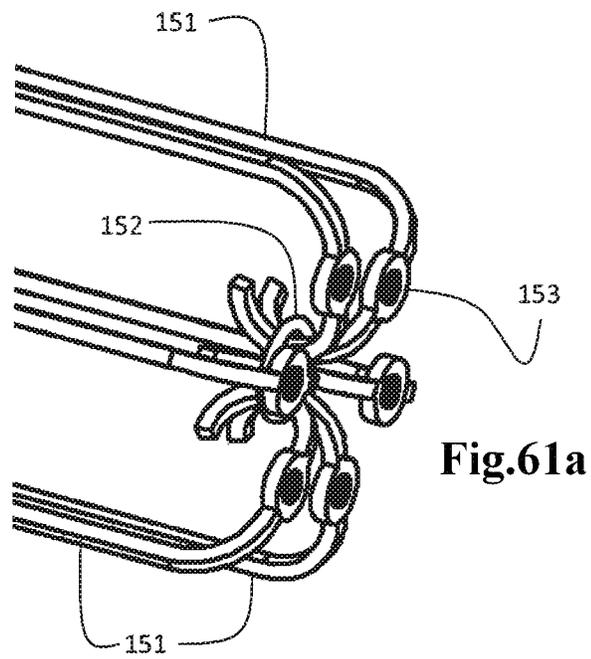
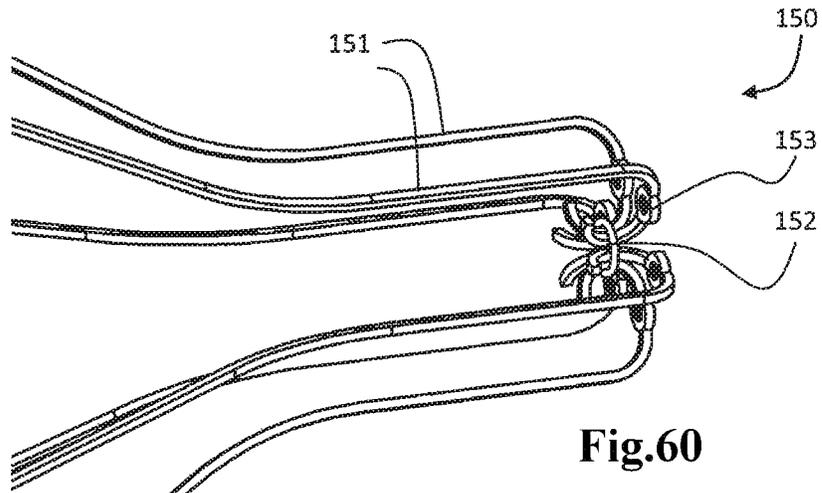


Fig. 55





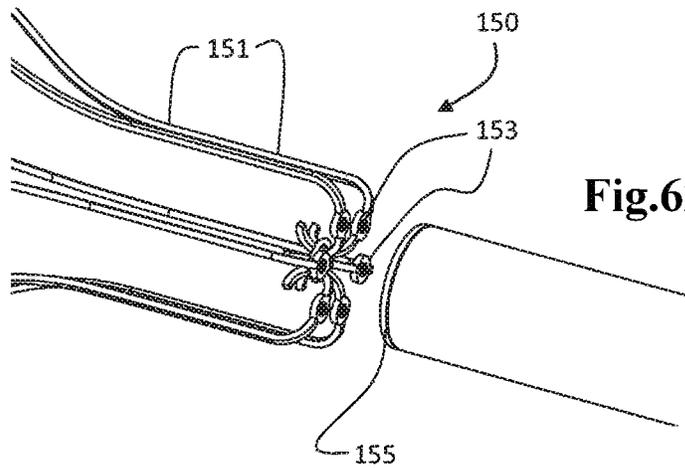


Fig. 62a

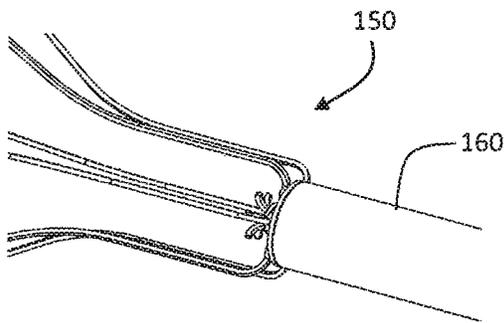


Fig. 62b

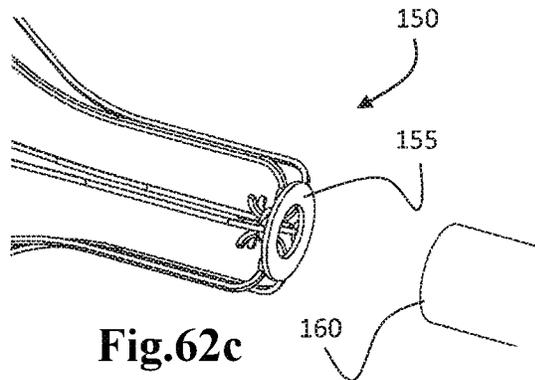


Fig. 62c

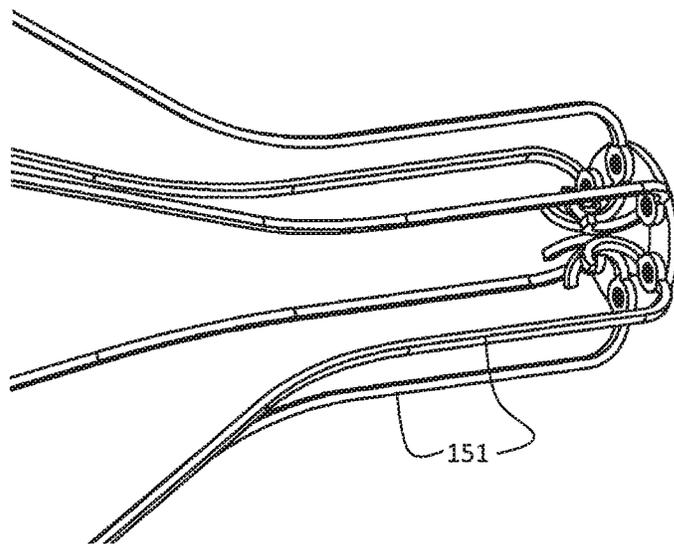


Fig. 62d

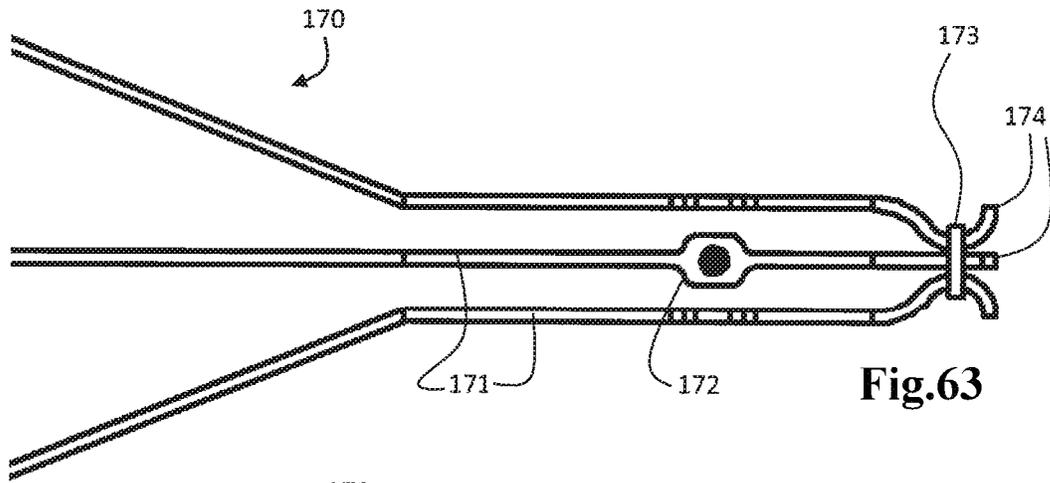


Fig. 63

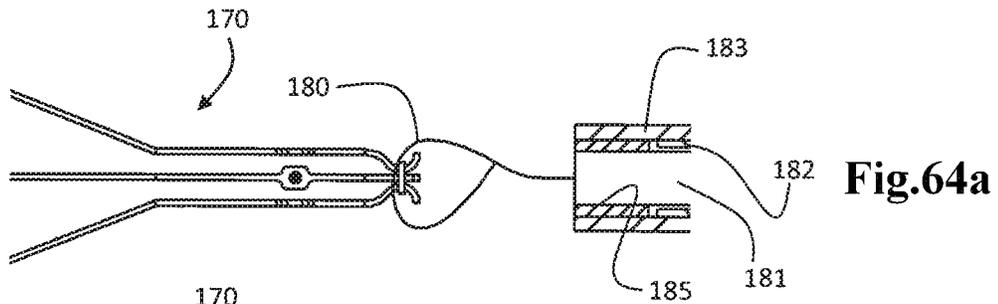


Fig. 64a

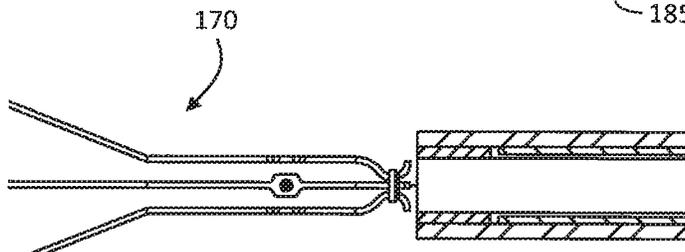


Fig. 64b

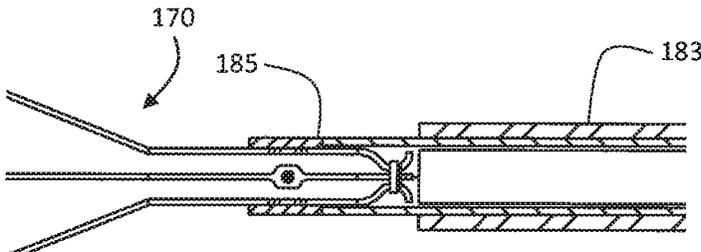


Fig. 64c

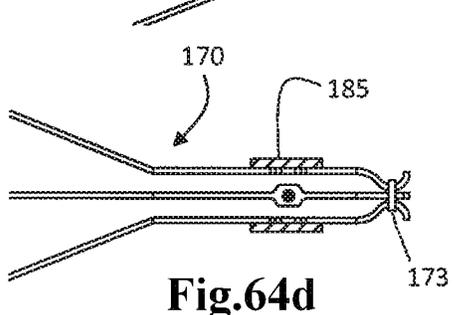


Fig. 64d

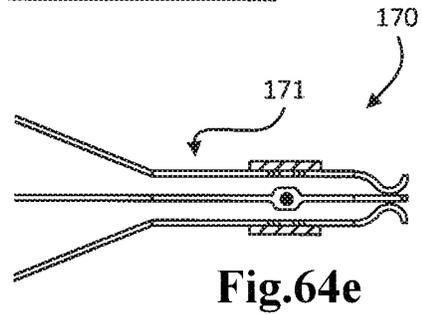


Fig. 64e

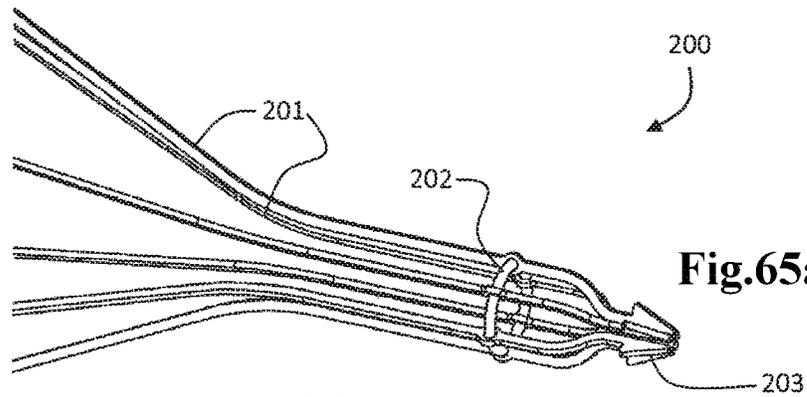


Fig.65a

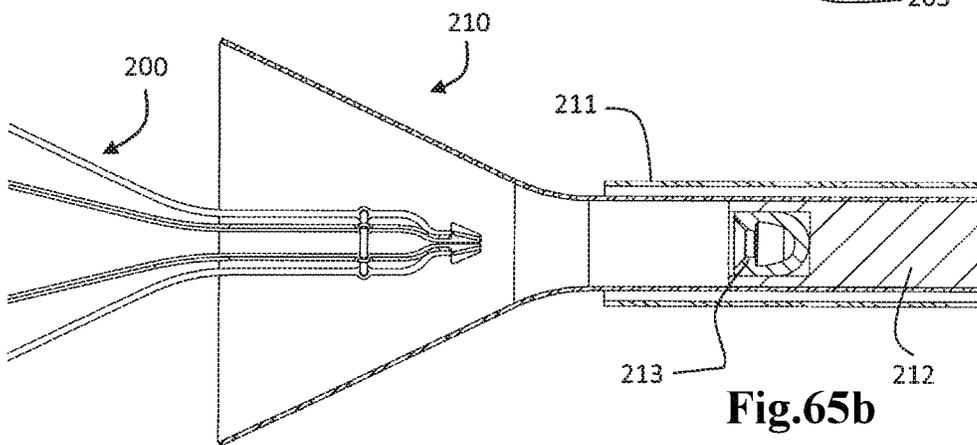


Fig.65b

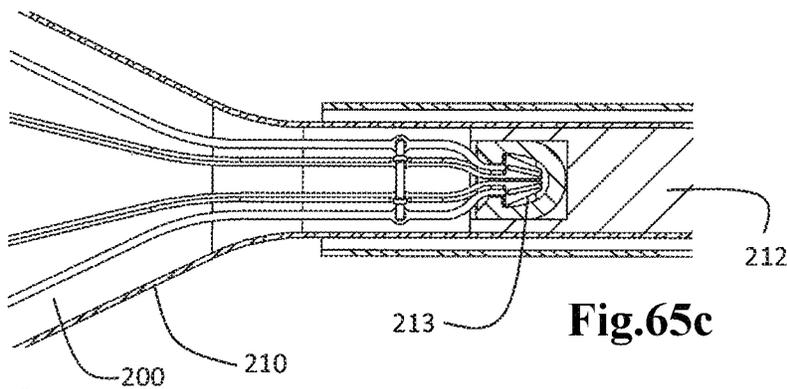


Fig.65c

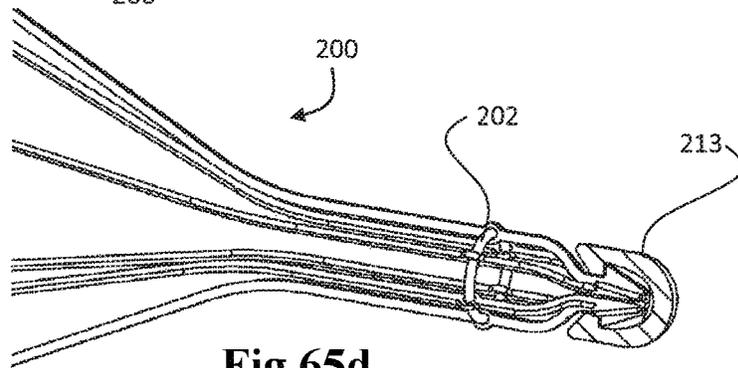


Fig.65d

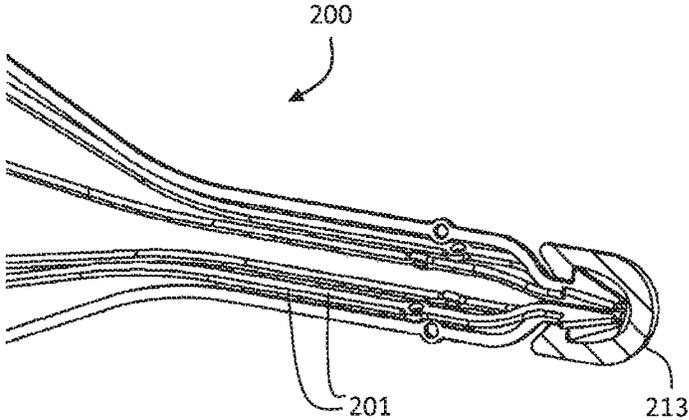


Fig.66a

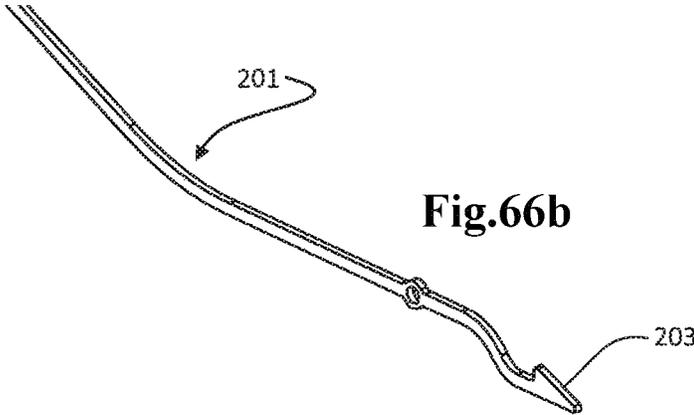


Fig.66b

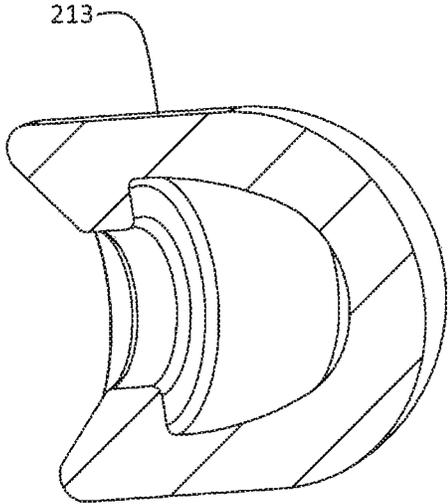


Fig.66c

VASCULAR FILTER SYSTEM

RELATED APPLICATIONS

This application is a continuation of U.S. Nonprovisional application Ser. No. 12/688,173, filed on Jan. 15, 2010, which claims the benefit of priority from U.S. Provisional Application No. 61/145,387, filed on Jan. 16, 2009, the entireties of each of which are incorporated herein by reference.

INTRODUCTION

This invention relates to a vascular filter system.

WO2008/010197 describes a vascular filter having filter elements which are held by a holder in a closed state for capturing thrombus passing through a blood vessel. The filter opens when the holder biodegrades after a predetermined period of time.

The invention is directed towards providing more versatility in use of a filter after delivery.

SUMMARY OF THE INVENTION

According to the invention, there is provided a vascular filter system comprising a vascular filter comprising at least one filter element, the filter being movable from a closed state for capturing thrombus passing through a blood vessel to an open state facilitating unrestricted blood flow. There may be a holder for holding the filter in the closed state for a predetermined period of time. There may be a member to at least temporarily extend the filtration period.

In one embodiment, the member comprises a retainer to at least temporarily retain the filter in the closed state beyond elapse of the predetermined period of time.

In one embodiment, the retainer is extendable around at least part of the filter to retain the filter in the closed state. In one embodiment, the retainer is adapted to clamp at least part of the filter to retain it in the closed state. In one embodiment, the retainer is adapted to tie at least part of the filter to retain it in the capturing state. In one embodiment, the retainer is configured to be located in the region of the centre of the filter. In one embodiment, the retainer is configured to be located in the region of the side of the filter. In one embodiment, at least part of the retainer is biodegradable and/or bioabsorbable. In one embodiment, the retainer is biostable. In one embodiment, the retainer is movable between a delivery state and a retaining state.

In one embodiment, the retainer is biased towards the retaining state. In one embodiment, the system comprises a delivery mechanism to deliver the retainer to the filter located in the blood vessel. In one embodiment, the delivery mechanism is adapted to maintain the position of the filter relative to a blood vessel during delivery of the retainer. In one embodiment, the delivery mechanism is adapted to grasp the filter for delivery of the retainer. In one embodiment, the retainer is configured to releasably retain the filter in the closed state. In one embodiment, the retainer is changeable, when engaging the filter, from a non-retaining state in which the filter is not retained to a retaining state in which the filter is retained. In one embodiment, the retainer is changeable from the non-retaining state to the retaining state responsive to an external intervention. In one embodiment, the retainer is changeable by rotation on threads to move with respect to the filter. In one embodiment, the retainer is changeable by insertion of a magnetic part to retain the filter.

In one embodiment, the retainer comprises first magnetic parts on the filter elements and a second magnetic part for engagement with the first magnetic parts to retain the filter elements in the closed state. In one embodiment, the first magnetic parts are located on the filter elements so that they are in a plane when the filter is in the closed state, and the second magnetic part has a planar face for contacting the first magnetic parts. In one embodiment, the second magnetic part is annular or disc-shaped.

In one embodiment, the system comprises a delivery assembly including a delivery catheter having a magnetic attraction to the second magnetic part which is less than the magnetic attraction between the first magnetic parts and the second magnetic part.

In one embodiment, the second magnetic part is sleeve-shaped, and the first magnetic parts are arranged in a ring which fits within the sleeve when the filter is in the closed state.

In one embodiment, the retainer is cup-shaped and configured to snap-fit around the ends of the filter elements. In one embodiment, the filter elements have arrow-shaped tips to fit behind a rim of the retainer. In one embodiment, the filter is biased towards the open state.

In one embodiment, at least part of the retainer is extendable through an opening between adjacent filter elements to retain the filter elements in the closed state beyond elapse of the predetermined period of time.

In one embodiment, at least part of the retainer is extendable through an opening in a filter element to retain the filter elements in the closed state beyond elapse of the predetermined period of time.

In one embodiment, in the closed state the filter elements extend towards an apex. In one embodiment, the retainer is configured to be located in the region of the apex. In one embodiment, the retainer is configured to be located in the region of the end of the filter element opposite to the apex.

In one embodiment, at least part of the holder is biodegradable and/or bioabsorbable upon elapse of the predetermined period of time.

In one embodiment, the filter comprises a vena cava filter.

In another aspect, the invention provides a method for treating a blood vessel, the method comprising the steps of:—

locating a vascular filter in the blood vessel, the vascular filter comprising at least one filter element, the filter being movable after a predetermined period of time from a closed state for capturing thrombus passing through the blood vessel to an open state facilitating unrestricted blood flow, and

a retainer at least temporarily retaining the filter in the capturing state beyond elapse of the first predetermined period of time.

In one embodiment, the method comprises the step of delivering the retainer to the filter. In one embodiment, the retainer is delivered to the filter after the filter has been located in the blood vessel. In one embodiment, the retainer is delivered to the filter using a delivery mechanism, and the method comprises the step of centering the delivery mechanism in the blood vessel. In one embodiment, the method comprises the step of maintaining the position of the filter relative to the blood vessel during delivery of the retainer.

In one embodiment, the method comprises the step of grasping the filter before delivering the retainer. In one embodiment, the method comprises the step of changing the retainer while it engages the filter from a non-retaining state in which the filter is not retained to a retaining state in which the filter is retained.

In one embodiment, the retainer is changed from the non-retaining state to the retaining state by external intervention. In one embodiment, the retainer is moved with respect to the filter.

In one embodiment, the retainer is rotated to move on threads. In one embodiment, the retainer is pushed or pulled with respect to the filter.

In one embodiment, the intervention includes inserting a retainer magnetic part for retaining the filter elements in the closed state. In one embodiment, the method comprises the step of extending the retainer around at least part of the filter. In one embodiment, at least part of the retainer biodegrades and/or is bioabsorbed upon elapse of a second predetermined period of time. In one embodiment, the method comprises the step of removing the retainer from the filter.

A vascular system configured to replace bioresorbable materials in vascular devices with a biostable component.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:

FIG. 1 is a side view of a vascular filter part of a vascular filter system according to the invention located in a blood vessel,

FIGS. 2 to 8 are side views of the vascular filter part of FIG. 1 in use in the blood vessel,

FIG. 9 is an isometric view of a retaining means part of the vascular filter system according to the invention in a delivery configuration,

FIG. 10 is an isometric view of the retaining means part of FIG. 9 in a retaining configuration,

FIGS. 11 to 18 are cross sectional side views of the vascular filter part of FIG. 1 and the retaining means part of FIG. 9 in use,

FIGS. 19 and 20 are views similar to FIGS. 9 and 10 of a retaining means part of another vascular filter system according to the invention,

FIGS. 21 and 22 are views similar to FIGS. 9 and 10 of a retaining means part of another vascular filter system according to the invention,

FIGS. 23 and 24 are views similar to FIGS. 9 and 10 of a retaining means part of another vascular filter system according to the invention,

FIG. 25 is a view similar to FIG. 18 of another vascular filter system according to the invention in use,

FIGS. 26 to 29 are views similar to FIGS. 11 to 13(b) of another vascular filter system according to the invention in use,

FIGS. 29(a) to 29(d) are views similar to FIGS. 11 to 13(b) of another vascular filter system according to the invention in use,

FIGS. 29(e) to 29(g) are views similar to FIGS. 14 to 18 of another vascular filter system according to the invention in use,

FIG. 29(h) is an isometric view of a vascular filter part of another vascular filter system according to the invention,

FIG. 29(i) is a cross sectional side view of the vascular filter system according to the invention in use,

FIG. 29(j) is a side view of the vascular filter system of FIG. 29(i),

FIG. 29(k) is an end view of the vascular filter system of FIG. 29(i),

FIG. 29(l) is a side view of another vascular filter system according to the invention in a non-retaining configuration,

FIG. 29(m) is an isometric view of the vascular filter system of FIG. 29(l) in a retaining configuration,

FIG. 29(n) is an isometric view of a vascular filter part of another vascular filter system according to the invention,

FIG. 29(o) is an isometric view of a retaining means part of the vascular filter system according to the invention,

FIG. 29(p) is a cross sectional side view of the vascular filter part of FIG. 29(n) and the retaining means part of FIG. 29(o),

FIGS. 30 to 32 are views similar to FIGS. 11 to 13(b) of another vascular filter system according to the invention in use,

FIG. 33 is an end view of a vascular filter part of the vascular filter system of FIGS. 30 to 32,

FIGS. 34 to 37 are views similar to FIGS. 11 to 13(b) of a retaining means part of the vascular filter system of FIGS. 30 to 32 in use,

FIG. 37(a) is an isometric view of a retaining means part of another vascular filter system according to the invention,

FIGS. 38 to 41 are views similar to FIGS. 11 to 13(b) of another vascular filter system according to the invention in use,

FIG. 42 is an isometric view of a retaining means part of the vascular filter system of FIGS. 38 to 41,

FIG. 43 is a side view of a retaining means part of another vascular filter system according to the invention,

FIGS. 44(a) to 44(d) are side views of retaining means parts of other vascular filter systems according to the invention,

FIG. 45 is an isometric view of a vascular filter part of another vascular filter system according to the invention,

FIGS. 46 and 47 are isometric views of part of the vascular filter part of FIG. 45,

FIG. 48 is an isometric view of the vascular filter part of FIG. 45 and a retaining means part of the vascular filter system before elapse of a predetermined period of time,

FIG. 49 is an isometric view of the vascular filter part of FIG. 45 and the retaining means part of FIG. 48 after elapse of the predetermined period of time,

FIGS. 50 and 51 are views similar to FIGS. 11 to 13(b) of another vascular filter system according to the invention in use,

FIGS. 52 to 55 are isometric views of the vascular filter system of FIGS. 50 and 51 in use,

FIG. 56 is a cross sectional side view of another vascular filter system according to the invention,

FIGS. 57 to 59 are views similar to FIG. 56 of other vascular filter systems according to the invention,

FIG. 60 is a perspective view of a filter with magnetic retainer elements, and FIGS. 61a-61c show the filter in more detail together with a second magnetic part delivered by a catheter, and FIGS. 62a-62d show delivery of the second retainer part;

FIG. 63 is a side view of a further filter of the invention, and FIG. 64a-64e show delivery of a sleeve-shaped magnetic retainer by a catheter;

FIGS. 65a-65d are a set of views showing an alternative filter of the invention onto which a cup-shaped retainer is placed by a catheter, and

FIGS. 66a-66c are a set of views showing the filter elements and the retainer in more detail.

DETAILED DESCRIPTION

Referring to the drawings, and initially to FIGS. 1 to 18 thereof, there is illustrated a vascular filter system according

to the invention. The vascular filter system comprises a vascular filter 1, a retainer 10, and a delivery catheter 11.

The vascular filter 1 is suitable for use as an inferior vena cava filter in the inferior vena cava 2. When used without the retainer 10, the filter 1 is movable from a closed state (FIG. 4) to an open state (FIG. 7) upon elapse of a predetermined period of time. In the closed state the filter 1 captures thrombus passing through the inferior vena cava 2 towards the heart and the lungs (FIG. 5). The filter 1 may thus be used to prevent pulmonary embolism. In the open state the filter 1 facilitates unrestricted blood flow.

As illustrated in FIG. 1, the filter 1 comprises a proximal support hoop 3 at the proximal end of the filter 1, a distal support hoop 4 at the distal end of the filter 1, and a plurality of support struts 5 extending between the proximal support hoop 3 and the distal support hoop 4.

In this patent specification, the terms ‘proximal’ and ‘distal’ are used in the sense that a proximal part is upstream of a distal part with reference to the direction of blood flow.

The proximal support hoop 3 comprises a wire element which extends circumferentially around the internal wall of the inferior vena cava 2 in a sinusoid wave pattern. Similarly the distal support hoop 4 comprises a wire element which extends circumferentially around the internal wall of the inferior vena cava 2 in a sinusoid wave pattern. The support struts 5 extend longitudinally along the internal wall of the inferior vena cava 2. The support struts 5 connect the proximal support hoop 3 to the distal support hoop 4. In this case the proximal support hoop 3, the distal support hoop 4 and the support struts 5 are formed integrally. The proximal support hoop 3, the distal support hoop 4 and the support struts 5 may be of a shape-memory material, such as Nitinol™.

As illustrated in FIG. 1, the filter 1 comprises twelve filter elements 6 for capturing thrombus passing through the inferior vena cava 2. Each filter element 6 is formed integrally with the proximal support hoop 3.

In the closed state the filter elements 6 extend in a substantially straight line to an apex 7, where the filter elements 6 engage each other. In this manner the filter elements 6 define a generally conically shaped capture region 8 within which thrombus may be captured. When the filter 1 is deployed in the inferior vena cava 2, the apex 7 is substantially in-line with the longitudinal axis extending through the centre of the inferior vena cava 2, and the capture region 8 is located in the region of the centre of the inferior vena cava 2. When the filter 1 is deployed in the inferior vena cava 2, the filter elements 6 extend in the direction of blood flow through the inferior vena cava 2.

The distal end of the distal support hoop 4 is located distally of the filter elements 6 and the apex 7, and the proximal end of the proximal support hoop 3 is located proximally of the filter elements 6.

When used without the retainer 10, the filter elements 6 are movable from the closed state to the open state upon elapse of the predetermined period of time. The filter elements 6 are biased towards the open state, and a holder is provided at the distal ends of the filter elements 6 to temporarily hold the filter elements 6 in the closed state until elapse of the predetermined period of time. The holder is biodegradable and/or bioabsorbable upon elapse of the predetermined period of time. When used without the retainer 10, upon biodegrading/bioabsorbing of the holder, the filter elements 6 are free to move from the closed state to the open state. The filter elements 6 are not biodegradable or bioabsorbable.

The holder may be provided in the form of a holder tube, or alternatively in the form of a holder suture extended through an opening at the distal end of each of the filter elements 6.

The filter 1 is movable between a collapsed delivery state and an expanded deployed state. The filter 1 is biased radially outwardly towards the deployed state. When the filter 1 is deployed in the inferior vena cava 2, the support hoops 3, 4 exert a force radially outwardly on the internal wall of the inferior vena cava 2. In this manner the support hoops 3, 4 support the filter elements 6 in position relative to the wall of the inferior vena cava 2.

The retainer 10 acts to at least temporarily retain the filter 1 in the closed state beyond elapse of the predetermined period of time.

In this case the retainer 10 is provided in the form of a clamp tube. The clamp tube is movable between a delivery state (FIG. 9) and a retaining state (FIG. 10). The clamp tube 10 is biased towards the retaining state.

In the retaining state the clamp tube 10 extends around the distal ends of the filter elements 6 of the filter 1 to retain the filter 1 in the closed state (FIG. 13(b)) beyond elapse of the predetermined period of time. In particular, in the retaining state the clamp tube 10 engages with the filter elements 6 of the filter 1 to clamp the filter 1 in the closed state. In the retaining state the clamp tube 10 is located in the region of the apex 7 of the filter 1 at the centre of the filter 1.

Because of the presence of the clamp tube 10, the filter elements 6 are no longer free to move from the closed state to the open state upon elapse of the predetermined period of time. Upon biodegrading/bioabsorbing of the holder, the filter elements 6 of the filter 1 are retained in the closed state by the clamp tube 10. In this manner the period of time in which the filter 1 captures thrombus is extended either temporarily or permanently.

The clamp tube 10 may be biodegradable and/or bioabsorbable. This results in a temporary extension of the period of time in which the filter 1 may capture thrombus. Alternatively the clamp tube 10 may be biostable. This results in a permanent extension of the period of time in which the filter 1 may capture thrombus. The temporary filter 1 may be converted into a permanent filter, or the life of the filter 1 may be prolonged.

An inclined lip 12 is provided at the distal end of each filter element 6. The lips 12 are engagable with the clamp tube 10 in the retaining configuration to releasably couple the clamp tube 10 in position around the distal ends of the filter elements 6 of the filter 1 (FIG. 13(b)).

As illustrated in FIGS. 14 to 18, the lips 12 may be invertible to facilitate selective removal of the clamp tube 10 from the distal ends of the filter elements 6 of the filter 1.

The delivery catheter 11 is employed to deliver the clamp tube 10 to the filter 1 after the filter 1 has been deployed in the inferior vena cava 2. The delivery catheter 11 comprises an inner tube 15 upon which the clamp tube 10 is mounted in the delivery configuration, an outer sheath 14, a pusher member 13 intermediate the inner tube 15 and the outer sheath 14, and a grasping wire 16 for grasping the distal ends of the filter elements 6 of the filter 1. The grasping wire 16 may be used to maintain the position of the filter 1 relative to the inferior vena cava 2 during delivery of the clamp tube 10. A recess 17 is provided at the proximal end of the inner tube 15 to facilitate positioning of the clamp tube 10 around the distal ends of the filter elements 6 of the filter 1 (FIG. 12).

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In use, the filter **1** is collapsed to the delivery state, and at least partially loaded into a delivery catheter. The delivery catheter is advanced through the inferior vena cava **2** until the collapsed filter **1** reaches the desired location in the inferior vena cava **2** (FIG. 2). A restraining sheath of the delivery catheter is then moved relative to the filter **1** to fully uncover the filter **1** (FIG. 3). Due to the biasing nature of the filter **1**, the filter **1** moves from the collapsed delivery state to the expanded deployed state (FIG. 4). In the deployed state, the support hoops **3, 4** exert a radially outward force on the internal wall of the inferior vena cava **2** to support the filter elements **6** in the desired position in the inferior vena cava **2**.

In the event of thrombus passing through the inferior vena cava **2** towards the heart and the lungs, the thrombus will be captured in the capture region **8** of the filter **1** (FIG. 5). The thrombus will thus be prevented from passing into the heart and the lungs which could otherwise lead to pulmonary embolism. The captured thrombus will gradually be broken down by the body into smaller size particles which will significantly reduce the risk of embolism (FIG. 6).

The holder temporarily holds the filter elements **6** in the closed state until elapse of the predetermined period of time. Before elapse of the predetermined period of time, the clamp tube **10** is mounted in the delivery state on the inner tube **15** of the delivery catheter **11**. The delivery catheter **11** is advanced through the inferior vena cava **2** until the clamp tube **10** reaches the distal ends of the filter elements **6** of the filter **1**, which has previously been deployed in the inferior vena cava **2** (FIG. 11). The grasping wire **16** is looped around the distal ends of the filter elements **6** of the filter **1** to hold the filter **1** relative to the delivery catheter **11** and to maintain the position of the filter **1** relative to the inferior vena cava **2** (FIG. 11). The outer sheath **14** is retracted to uncover the clamp tube **10** (FIG. 12). The delivery catheter **11** is advanced further through the inferior vena cava **2** until the lips **12** are within the recess **17** (FIG. 12). The pusher member **13** is moved proximally relative to the inner tube **15** until the clamp tube **10** is positioned around the distal ends of the filter elements **6** of the filter **1**. Due to the biasing nature of the clamp tube **10**, the clamp tube **10** moves from the delivery state to the retaining state (FIG. 13(a)).

In the retaining state the clamp tube **10** engages with the filter elements **6** of the filter **1** to clamp the filter **1** in the closed state beyond elapse of the predetermined period of time. Upon elapse of the predetermined period of time the holder biodegrades/bioabsorbs. The filter elements **6** of the filter **1** are retained in the closed state by the clamp tube **10**. In this manner the period of time in which the filter **1** captures thrombus is extended either temporarily or permanently.

In the case where the clamp tube **10** is biodegradable and/or bioabsorbable, the clamp tube **10** biodegrades/bioabsorbs upon elapse of a further predetermined period of time. This enables the filter elements **6** to move from the closed state to the open state (FIG. 7). In the open state the filter **1** facilitates unrestricted blood flow. The support hoops **3, 4** and the filter elements **6** remain in the inferior vena cava **2** (FIG. 8).

In the case where the clamp tube **10** is biostable, the filter **1** is permanently retained in the closed state (FIG. 6).

In the case of either the biodegradable/bioabsorbable clamp tube **10** or the biostable clamp tube **10**, to remove the clamp tube **10** from the distal ends of the filter elements **6** of the filter **1**, the grasping wire **16** is looped around the proximal end of the clamp tube **10** (FIG. 15). The grasping wire **16** is moved distally relative to the filter **1** to draw the

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clamp tube **10** distally causing inversion of the lips **12** (FIG. 16), and removal of the clamp tube **10** from the distal ends of the filter elements **6** of the filter **1** (FIG. 17). If the clamp tube **10** is removed after elapse of the predetermined period of time, the filter elements **6** move from the closed state to the open state (FIG. 7). In the open state the filter **1** facilitates unrestricted blood flow. The support hoops **3, 4** and the filter elements **6** remain in the inferior vena cava **2** (FIG. 8).

FIG. 11 illustrates the lasso/snare **16** threaded over the hooks **12** and tightened. Once the hooks **12** enter the hook dock **17** which occurs during tightening and prevents the biostable ring **10** from being deployed over the hooks **12**, the snare **16**, the centring shaft **15**, and the outer sheath **14** are held stationary while the pusher **13** is advanced to deploy the biostable ring **10** between the implant filtration elements **6** and the hooks **12**.

FIGS. 12 and 13(a) illustrate the biostable ring **10** moving from the undeployed expanded state to the deployed contracted state. The centring shaft **15** holds the biostable ring **10** in the expanded state during delivery. Once the pusher **13** advances the biostable ring **10** proximal to the centring shaft **15**, the biostable ring **10** reverts to its natural contracted state. This phase transition may be achieved through the use of a spring or shape memory material.

It may be desirable to remove the biostable ring **10** once the patient has fully recovered (FIG. 17). This can be achieved through the use of the snare **16**.

In order to prevent complications arising from the biostable ring **10** flowing loose in the venous system, a catch may be employed to aid retrieval of the biostable ring **10** (FIG. 18). The catch feature may be in the form of a retrieval catheter housed over the snare device **16** consisting of an expandable tip.

It will be appreciated that the retainer may be provided in any suitable form, for example a tubular mesh **20** (FIGS. 19 and 20), or a coil **21** (FIGS. 21 and 22), or a cut tube **22** (FIGS. 23 and 24).

The retainer **30** may comprise an engagable protrusion **31** around which the grasping wire **16** may be looped to assist removal of the retainer **30** from the distal ends of the filter elements **6** of the filter **1** (FIG. 25). The catch feature may be in the form of the hook **31** connected/formed as part of the ring **30**. This embodiment may also encompass a receiver mouth on the distal end of the snare catheter to facilitate removal of the biostable ring **30**.

In FIGS. 26 to 29 there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. 1 to 18, and similar elements in FIGS. 26 to 29 are assigned the same reference numerals.

In this case the retainer **40** is provided in the form of a clamp tube. The clamp tube has the same configuration both during delivery (FIG. 26) and during retaining (FIG. 29).

As illustrated in FIG. 28, the lips **12** are deformable to facilitate location of the clamp tube **40** around the distal ends of the filter elements **6** of the filter **1**.

The grasping wire **16** may be used to maintain the position of the filter **1** relative to the inferior vena cava **2** during delivery of the clamp tube **40**. In use, the grasping wire **16** is looped around the distal ends of the filter elements **6** of the filter **1** to hold the filter **1** relative to the delivery catheter **11** and to maintain the position of the filter **1** relative to the inferior vena cava **2** (FIG. 27). In order to prevent the support rings **3, 4** and barbs from being pulled distally or pushed proximally or vice versa depending on the direction of approach of the delivery catheter **11**, the delivery mechanism **11** is provided in such a way as to balance the forces applied to the filter elements **6**. For example, when pushing

the clamp tube **40** over the apex endings, a simultaneous pull force is applied to the hook integral with the filter elements **6**. The push force is applied with the pusher **13**, and the pull force is applied with the snare **16**. This force balancing may be incorporated into any of the embodiments disclosed herein from a proximal or distal approach. This arrangement prevents damage to the vessel wall during application of the secondary restraint **40**.

The snare/lasso **16** is threaded over the distal books and tightened (FIG. **27**). This centres the conversion catheter assembly **11** and holds the implant filtration elements **6** stationary while the biodegradable conversion ring **40** is translated over the retainers **12**. Once tightened, the proximal end of the snare **16** and the snare outer tube **14** are held stationary while the pusher **13**, and the extension ring **40** are advanced until the extension ring **40** is locked in position between the two sets of retainers **12**.

The tip of the outer sheath **14** may encompass an expandable tip that allows the extension ring **40** to be advanced through it with force but not without force. This serves as a safety feature preventing the extension ring **40** from being detached prematurely.

The invention enables the filter **1** to be converted into a permanent filter if the indications for the patient changed or were incorrectly assessed at the time of implant. A means of achieving this is to use a catheter to place a cap, tie or other locking mechanism at the apex **7** of the filter **1** to hold the convertible filter elements **6** in the filter configuration permanently. This may be achieved using the catheter **11** which gains access to the venous system by percutaneous access and delivers the locking mechanism **40** to the filter site.

The hook is incorporated into the apex region **7** which may be engaged with the snare component **16** that is delivered from the distal side of the filter **1** (FIGS. **26** to **29**). Snaring the hook allows the catheter **11** to be positioned accurately at the apex **7** of the filter **1**. The catheter **11** houses the fixing component **40** to convert the filter **1** into a permanent device.

Once the hook is engaged and the snare **16** retracted, the outer tube **14** can be slid over the apex region, this will ensure good alignment and minimise any risk of the fixing component **40** becoming an embolus. The fixing component **40** is then pushed forward and released so that it engages the apex region **7** of the filter **1** constraining the filter elements **6** of the device **1** so that they cannot return to the vessel wall. The distal end of the apex region **7** includes the feature **12** that prevents the fixing component **40** moving distally.

In order for the fixing component **40** to engage in its final position it needs to navigate past this feature **12**. This could be achieved by designing the component **40** to be held at a larger diameter in the catheter **11** but once it is released it springs back to a smaller diameter engaging with the filter **1** sufficiently to achieve a permanent attachment. Means of achieving this could be by using a coiled spring, a lattice or trellis type arrangement, or by using a slit tube. The fixing device **40** may also be inherently flexible to be pushed over the snap fit feature **12** into its final position.

FIGS. **29(a)** to **29(d)** illustrate another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **26** to **29**, and similar elements in FIGS. **29(a)** to **29(d)** are assigned the same reference numerals.

In this case each filter element **6** comprises a finger **121** protruding radially inwardly.

In the retaining state the clamp tube **120** extends around the fingers **121** of the filter elements **6** of the filter **1** to retain the filter **1** in the closed state (FIG. **29(c)**) beyond elapse of

the predetermined period of time. In particular, in the retaining state the clamp tube **120** engages with the fingers **121** of the filter elements **6** to clamp the filter **1** in the closed state. In the retaining state the clamp tube **120** is located in the region of the apex **7** of the filter **1** at the centre of the filter **1**. The clamp tube **120** is located radially inwardly of the filter elements **6** of the filter **1** (FIG. **29(c)**). The filtration arms **6** extend along the outer surface of the internal restraint **120**.

Because of the presence of the clamp tube **120**, the filter elements **6** are no longer free to move from the closed state to the open state upon elapse of the predetermined period of time. Upon biodegrading/bioabsorbing of the holder **122**, the filter elements **6** of the filter **1** are retained in the closed state by the clamp tube **120** (FIG. **29(d)**). In this manner the period of time in which the filter **1** captures thrombus is extended either temporarily or permanently.

As illustrated in FIG. **29(b)**, the lips **12** are deformable to facilitate location of the clamp tube **120** around the fingers **121** of the filter elements **6** of the filter **1**.

Referring to FIGS. **29(e)** to **29(g)** there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **29(a)** to **29(d)**, and similar elements in FIGS. **29(e)** to **29(g)** are assigned the same reference numerals.

In this case the lips **12** are deformable to facilitate location of the clamp tube **130** around the fingers **121** of the filter elements **6** of the filter **1**, and to facilitate selective removal of the clamp tube **130** from the fingers **121**.

The clamp tube **130** comprises an engagable protrusion **131** around which the grasping wire **16** may be looped to assist removal of the clamp tube **130** from the fingers **121**.

To remove the clamp tube **130** from the fingers **121**, the grasping wire **16** is looped around the protrusion **131** (FIG. **29(f)**). The grasping wire **16** is moved proximally relative to the filter **1** to draw the clamp tube **130** proximally causing deformation of the lips **12** (FIG. **29(g)**), and removal of the clamp tube **130** from the fingers **121**.

The proximal hook **131** is integral with the secondary restraint **130** and facilitates removal of the permanent/bioresorbable secondary restraint **130** when the need for filtration ceases.

In FIGS. **29(h)** to **29(k)** there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **26** to **29**, and similar elements in FIGS. **29(h)** to **29(k)** are assigned the same reference numerals.

In this case the filter **1** comprises a threaded docking member **141** at the distal end of the filter **1**. The clamp tube **140** is also threaded. The docking member **141** is engagable with the clamp tube **140** by means of the threaded formations to releasably couple the clamp tube **140** in position around the distal ends of the filter elements **6** of the filter **1** (FIG. **29(j)**). The threaded nature of the docking member **141** and the clamp tube **140** facilitates selective removal of the clamp tube **140** from the distal ends of the filter elements **6** of the filter **1**.

In this thread arrangement the nut **140** is employed to extend the period of protection. The nut **140** may be in place upon initial intervention or attached at the time of extension.

The apex arms **6** are retained for the initial period of protection by the bioresorbable coupling means. The apex arms **6** are passed through slots in the biostable tube **141** with an outer thread. One of the slots is closed. The apex arm **6** extending through the closed slot is formed into a lip to hold the threaded tube **141** in place. Upon elapse of the predetermined protection period, the bioresorbable coupling

means breaks and the capture and apex arms 6 revert to their radially biased state. The biostable tube 141 is retained on the apex arm 6 with the lip and becomes endothelialized at the vessel wall. Alternatively if the need for protection persists, the bioresorbable or biostable nut 140 may be threaded over the biostable tube 141 to extend the period of protection. If a biostable nut 140 is used, it is possible to remove the nut 140 by means of a retrieval system.

The nut 140 may be delivered to the device 1 by means of the catheter system 11. The catheter 11 encompasses a funnel, the centering nose 15, the snare 16, and the outer sheath 14 with a socket to assist in threading the nut 140 over the threaded tube 141.

FIGS. 29(l) and 29(m) illustrate another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. 29(h) to 29(k), and similar elements in FIGS. 29(l) and 29(m) are assigned the same reference numerals.

In this case the clamp tube 140 is movable proximally from a non-retaining position (FIG. 29(l)) to a retaining position (FIG. 29(m)) by rotating the clamp tube 140 relative to the docking member 141.

In the non-retaining position the clamp tube or nut 140 is mounted to the docking member 141 distally of the distal end 150 of each of the filter elements 6 of the filter 1. In the non-retaining position the filter 1 is not retained in the closed state by the clamp tube 140.

In the retaining position the clamp tube 140 is mounted to the docking member 141 proximally of the distal end 150 of each of the filter elements 6 of the filter 1. In the retaining position the filter 1 is retained in the closed state by the clamp tube 140. The clamp tube 140 extends around the filter elements 6 of the filter 1 to retain the filter 1 in the closed state beyond elapse of the predetermined period of time. In particular, in the retaining position the clamp tube 140 engages with the filter elements 6 of the filter 1 to clamp the filter 1 in the closed state.

The nut 140 is preloaded on the biostable tube 141. The threaded tube 141 extends distally of the apex arms 6 so that the preloaded nut 140 does not retain the apex arms 6 (FIG. 29(l)).

The nut 140 may be in the form of a common hexagonal nut or it may be a custom shape with features engagable with a custom designed socket.

Referring to FIGS. 29(n) to 29(p) there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. 29(h) to 29(k), and similar elements in FIGS. 29(n) to 29(p) are assigned the same reference numerals.

In this case the docking member 141 is not threaded. The clamp tube 160 is also not threaded. An inwardly protruding lip 161 is provided at the proximal end of the clamp tube 160. The docking member 141 is engagable with the clamp tube 160 in a snap-fit manner by means of the lip 161 to couple the clamp tube 160 in position around the distal ends of the filter elements 6 of the filter 1 (FIG. 29(p)).

The snap fit biostable restraint 160 is translated over the pre-loaded biostable tube 141 with slots for the apex arms 6. One of the slots is closed.

In another embodiment, a secondary retaining ring may be deployed from the proximal end into a snap fit arrangement integral with the filter apex. A proximal hook may be used to aid in grasping the filter 1 to locate the secondary restraint.

FIGS. 30 to 37 illustrate a further vascular filter system according to the invention, which is similar to the vascular

filter system of FIGS. 1 to 18, and similar elements in FIGS. 30 to 37 are assigned the same reference numerals.

In this case the retainer 50 is provided in the form of a clamp device. The clamp device 50 comprises a plurality of arms 111. The clamp device 50 is movable between an open state (FIG. 36) and a closed retaining state (FIG. 37) by operation of the delivery catheter 51.

As illustrated in FIG. 33, the twelve filter elements 6 are arranged into six pairs. For each pair, the distal tip of one filter element 6 is attached to the distal tip of the other filter element 6. In this manner a loop opening 100 is formed between each pair of filter elements 6.

In the retaining state the arms 111 of the clamp device 50 extend through the loop openings 100 between adjacent filter elements 6 of the filter 1 to retain the filter elements 6 of the filter 1 in the closed state (FIG. 32) beyond elapse of the predetermined period of time. In particular, in the retaining state the clamp device 50 engages with the filter elements 6 of the filter 1 to clamp the filter 1 in the closed state. The clamp device 50 is located in the region of the apex 7 of the filter 1 at the centre of the filter 1.

The delivery catheter 51 is employed to deliver the clamp device 50 to the filter 1 after the filter 1 has been deployed in the inferior vena cava 2. The delivery catheter 51 comprises an inner tube 52, an outer sheath 53, and an expandable member 54 at the distal end of an intermediate tube 55 upon which the clamp device 50 is mounted.

It will be appreciated that in the retaining state the arms 111 of the clamp device 50 may alternatively extend through an opening in a filter element 6 of the filter 1 to retain the filter elements 6 of the filter 1 in the closed state beyond elapse of the predetermined period of time.

In use, the clamp device 50 is mounted on the intermediate tube 55 of the delivery catheter 51. The delivery catheter 51 is advanced through the inferior vena cava 2 until the clamp device 50 reaches the distal ends of the filter elements 6 of the filter 1, which has previously been deployed in the inferior vena cava 2 (FIG. 30). The outer sheath 53 is retracted to uncover the clamp device 50 (FIG. 35). The inner tube 52 is moved proximally relative to the intermediate tube 55 to expand the expandable member 54 thereby moving the clamp device 50 from the closed retaining state to the open state (FIG. 36).

The delivery catheter 51 is advanced further through the inferior vena cava 2 until the arms 111 of the clamp device 50 extend through the loop openings 100 between adjacent filter elements 6 of the filter 1 (FIG. 31). The inner tube 52 is moved distally relative to the intermediate tube 55 to contract the expandable member 54 thereby moving the clamp device 50 from the open state to the closed retaining configuration (FIG. 37). In the retaining state the clamp device 50 engages with the filter elements 6 of the filter 1 to clamp the filter 1 in the closed state beyond elapse of the predetermined period of time (FIG. 32). Upon elapse of the predetermined period of time the holder biodegrades/bioabsorbs. The filter elements 6 of the filter 1 are retained in the closed state by the holder clamp device 50. In this manner the period of time in which the filter 1 captures thrombus is extended either temporarily or permanently.

As illustrated in FIG. 32, the claw type device 50 may be used to restrain the filtration elements 6 from opening. For insertion through the loops 100 of the filtration elements 6, the claw 50 is opened through shape memory or mechanical actuation, after which the claw 50 reverts to its closed state. The closed state may be achieved through shape memory properties or mechanical actuation. The proximal end of the

claw **50** may encompass a conical, spherical, or parabolic geometry in order to minimise stagnant areas and resistance to blood flow.

The vena cava filter **1** has the device **50** which can be used to change the filter **1** into a permanent filter if the indications of the patient changed or were incorrectly assessed at the time of implantation. A means of achieving this would be to use the catheter **51** to place a cap, tie or other locking mechanism at the apex **7** of the filter **1** to hold the absorbable filter elements **6** in the filter configuration permanently. This could be achieved using the catheter **51** which gains access to the venous system by percutaneous access and delivers the locking mechanism **50** to the filter site.

FIGS. **30** to **32** show the means of doing this using the grabbing type component **50**. The internal push rod **55** is advanced releasing the grabbing component **50** which was constrained in the sheath **53**. The grabbing component **50** has arms which engage with the filter frame **6** when advanced. The grabbing component **50** is then deformed back to a reduced diameter using the external tube or sheath **53**.

As illustrated in FIG. **33**, at the apex region **7** the neighbouring filter elements **6** are close or touching ensuring that the arms of the grabbing component **50** engage within the filter element **6** rather than through neighbouring elements **6**. The filtration elements **6** may be arranged to prevent the grabber **50** engaging between filtration elements **6**.

It may be possible to convert the filter **1** to a permanent filter from either the proximal or distal side facilitating an access route from the femoral or jugular vein. The claw **50** may be advanced from a proximal or distal approach. Opening of the claw **50** may be achieved mechanically through compression of the tube or ring of material **54**. Upon compression, the tube/ring **54** expands radially, thus opening the claw **50**. Once in position, the claw **50** is closed through release of the compressive force. To achieve the closing mechanism, the claw **50** may be manufactured from a shape memory or spring material.

The number of arms **111** of the clamp device may be varied as appropriate. For example the clamp device **110** of FIG. **37(a)** comprises seven arms **111**, and is suitable for use with the six pairs of filter elements **6**. By including more arms **111** on the clamp device **110** than loop openings **100** between the filter elements **6**, this results in a degree of redundancy to ensure that the arms **111** of the clamp device **110** will extend through the loop openings **100** to safely retain the filter elements **6** of the filter **1** in the closed state. Only one claw **111** needs to extend through a pair of joined filter elements **6**. The seven prong claw **110** will always catch with the filter **1** comprising six joined filter element pairs.

Referring to FIGS. **38** to **42** there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **1** to **18**, and similar elements in FIGS. **38** to **42** are assigned the same reference numerals.

In this case a retainer **60** is provided in the form of a tie element to tie the filter elements **6** of the filter **1** in the closed state beyond elapse of the predetermined period of time. The tie element **60** is of a flexible material that may be knotted. The tie element **60** is movable between an open delivery configuration (FIG. **39**) and a closed retaining configuration (FIG. **41**).

The delivery catheter **61** is employed to deliver the tie element **60** to the filter **1** after the filter **1** has been deployed in the inferior vena cava **2**.

The lasso **60** may be used to extend protection permanently/temporarily. The lasso **60** is advanced within the deployment catheter **61** from a proximal or distal approach. When it has engaged with the ends of the filtration elements **6**, it is tightened and detached from the catheter **61**.

The filter **1** may be changed into a permanent filter if the indications of the patient changed or were incorrectly assessed at the time of implant. A means of achieving this would be to use the catheter **61** to place a cap, tie or other locking mechanism at the apex **7** of the filter **1** to hold the absorbable filter elements **6** in the closed, capturing, state permanently. This could be achieved using the catheter **61** which gains access to the venous system by percutaneous access and delivers the locking mechanism **60** to the filter **1**.

To retain the tie **60** or cap at the apex region **7**, the elements **6** are extended past the apex point **7**.

The retainer **60** may be provided in the form of a helical coil or spring deployed from the catheter **61** to restrain the filter elements **6** from opening. Shape memory or spring materials may be used.

A potential means of doing this is by using the lasso type feature **60** which engages with the apex **7** of the filter **1** and is tightened to fix the filter **1** before the loop **60** is detached from the catheter **61**. The loop **60** could be designed with ratchet type features so it locks in place when it is being tightened (FIG. **43**). The taut loop **60** may be secured via a knot (FIG. **42**) or ratchet lasso/loop system (FIG. **43**). The taut secure loop/lasso **60** may be detached by a screw (FIG. **44(a)**), by a mechanical cut (FIG. **44(b)**), by shear load (FIG. **44(c)**), or by a tensile load system. The loop/noose **60** could be detached using a screw attachment (FIG. **44(a)**). Also a cutting mechanism may be designed into the catheter **61** to cut the noose (FIG. **44(d)**). It is also envisaged to have a reduced cross section beside the detachment point and provide an electric current to break the wire.

The loop of material for the lasso **60** can be made such that it would be bioabsorbable/biodegradable and thus extend the duration that the filter **1** will remain in the closed configuration. Alternatively the material may be a biostable material such that the filter **1** will not convert at any time.

The lip **12** may be formed integrally in the filter element **6**, as illustrated in FIGS. **45** to **49**. A method of manufacturing the filter **1** is shown in FIGS. **45** to **49**. Firstly a notch is machined in the strut **6** at the distal end of the filter **1** as shown in FIG. **46**. The tip of the filter arm **6** is then heat-set in a shape similar to that shown in FIG. **47**. FIG. **46** illustrates the strut **6** with the notch created, and FIG. **47** illustrates the strut **6** heat-set into position.

The filter element arms **6** may then be constrained together in the filtering closed state for the original period until elapse of the predetermined period of time using the holder **65** which may be provided in a variety of possible means, for example a piece of biodegradable suture tied at the ends. The holder **65** temporarily holds the filter elements **6** in the closed state until elapse of the predetermined period of time.

The notches on the filter element arms **6** provide a suitable anchoring location for the biostable or biodegradable retainer loop **60** to be deployed over the biodegradable holder **65** around the tips **12** and tightened down to hold the filter elements **6** temporarily or permanently in the filtering configuration beyond elapse of the predetermined period of time (FIG. **48**). The retainer **60** extends the period of filtration.

FIG. **45** illustrates the degradable holder **65** in place. FIG. **48** illustrates the secondary retainer **60** deployed over the

primary holder **65**. FIG. **49** illustrates the secondary retainer **60** after the primary holder **65** has bio-degraded/bio-absorbed.

It will be appreciated that a variety of types of tie element may be used to tie the filter elements **6** of the filter **1** in the closed state beyond elapse of the predetermined period of time.

It will be appreciated that a variety of types of retainer may be used to constrain the filter elements **6** of the filter **1** in the closed state beyond elapse of the predetermined period of time, for example a coil, loop, ring or cap.

In FIGS. **50** to **55** there is illustrated another vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **38** to **42**, and similar elements in FIGS. **50** to **55** are assigned the same reference numerals.

In this case the tie element **70** is woven around and through the filter elements **6** to tie the filter elements **6** of the filter **1** in the closed state beyond elapse of the predetermined period of time.

The delivery catheter **71** is employed to deliver the tie element **70** to the filter **1**. The delivery catheter **71** comprises an inflatable balloon **72** to assist in centering the delivery catheter **71** in the blood vessel **2** (FIG. **51**).

As illustrated in FIG. **51**, the coil deployment catheter **71** is advanced to the site of the implant **1** via a proximal approach until the distal tip is centred in the vessel **2** by the conical shape of the implant filtration elements **6**. The inflatable balloon **72** may be incorporated to aid centring of the catheter **71**. The catheter **71** may also be advanced from a distal approach.

The coil **70** is preprogrammed through shape memory to change direction/orientation as a length of the coil **70** is deployed (FIG. **52**). As the coil **70** changes direction, it winds itself in between the filtration elements **6** until a binding matrix is formed at the apex **7** of the filter portion. The coil matrix **70** restrains the filtration elements **6** from opening when the original biodegradable restraint finalises its degradation process. Once the coil **70** is deployed, the delivery catheter **71** is removed.

FIG. **56** illustrates a further vascular filter system according to the invention, which is similar to the vascular filter system of FIGS. **1** to **18**, and similar elements in FIG. **56** are assigned the same reference numerals.

In this case the retainer **80** is provided in the form of a support ring.

The support ring **80** extends around the proximal ends of the filter elements **6** of the filter **1** to retain the filter **1** in the closed state beyond elapse of the predetermined period of time. In particular, the support ring **80** engages with the filter elements **6** of the filter **1** to support the filter **1** in the closed state. The support ring **80** is located in the region of the end of the filter elements **6** opposite to the apex **7** of the filter **1** at the side of the filter **1**.

The support ring **80** may be inflatable via hydrogel or saline, or may be a solid ring. The support ring **80** may be deployed from a catheter within the filter **1** to restrain the filtration elements **6** at the wall of the vessel **2**, between the wall of the vessel **2**, or at the central axis of the vessel **2**.

The location of the retainer relative to the filter **1** may be varied, as illustrated in FIGS. **57** to **59**. The retainer may engage with the filter elements **6** of the filter **1** and/or with the support struts **5** of the filter **1** to support the filter **1** in the closed state. The retainer may extend along part or substantially all of the filter elements **6**. The retainer may be located at any suitable point along the filter elements **6**.

The restraining device may encompass supports extending distal and/or proximal of the restraint (FIG. **59**). This support may be in the form of a tubular mesh.

Referring to FIGS. **60** to **62** a filter **150** has filter elements **151** which are curved inwardly and proximally at their distal ends. The filter elements **151** are held in the closed state by a biodegradable holder **152**. Also, the filter elements **151** include retainer disc-shaped magnetic parts **153** located at the bends at the distal ends. The retainer also comprises a washer-shaped second part **155** which is delivered by a catheter **160** so that it engages the first magnetic parts **153**. The complete retainer thereby holds the filter elements in the closed state (FIGS. **62a-62d**). In more detail the magnetic inserts **153** may be positioned by heating the filter elements and then cooling to secure the magnetic inserts **153**. Alternatively, they could be bonded or crimped in place. The retainer second part **155** may be deployed without need for a snare or funnel guiding system, but these may be provided additionally if desired. During deployment of the retainer second part, the magnetic attraction between the part **155** and the filter elements is greater than that between the part **155** and the catheter. The retainer part **155** may be coupled to the catheter by an interference fit in place of or in addition to the magnetic attraction.

Referring to FIGS. **63** and **64a-64e**, a filter **170** has filter elements **171** held for a predetermined period of time by a biodegradable holder **173**. The filter elements **171** have bends at their distal ends, the bends being faced inwardly and the ends **174** of the elements **171** extending radially outwardly. Each filter element **171** has a retainer magnetic insert **172**. To extend the protection period, the filter element hook ends are grasped with a snare **180** which is tightened to bring the apex and the catheter into close contact. The catheter central shaft **181** and sheath **183** are held stationary and a pusher **182** advances a magnetic collar **185** over the filter element magnets **172**. The magnetic attraction forces prevent the collar **185** from slipping. The central shaft **181** may have a reception space for the filter element hook ends. The collar **185** is held in position in the delivery system by an interference fit or by a magnetic insert on the central shaft **181**. Alternatively, the collar **185** may be attached to the pusher by magnetism. Of course, in order for the pusher to release the collar **185**, the magnetic attraction force between the collar and the pusher should be less than that between the filter elements and the collar. The filter element ends may extend proximally in order for the extension step to be performed from a femoral approach.

Referring to FIGS. **65a-65d** and **66a-66c** a filter **200** comprises filter elements **201** held by a biodegradable holder **202**. The filter elements **201** terminate at the distal end with a tip **203** somewhat like an arrow head. For retaining the closed state beyond the predetermined period of time an expanded funnel **210** is moved by a catheter having a funnel sheath **211** and a central shaft **212**. The catheter delivers a retainer **213** which is cup-shaped, with an internal rim. For delivery, after the delivery system is advanced to the site, the self-expanding locating funnel **210** is expanded by retracting the sheath **211**. The funnel fits neatly over the, similarly shaped, filter. The assembly is advanced further and a slight force is applied for the retainer **213** to snap over the tips **203**. This force is low to avoid damage to the vessel wall. The assembly is retracted and the sheath is advanced to collapse the funnel before removing it from the patient. An offset lumen may be provided in the catheter to allow passage of a guide wire and/or snare. The retainer **213** may have a hook on the distal end to allow removal at a later stage. The retainer may have a reception space on the distal end (like

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a miniature version of that on the proximal side) so that it could be releasably attached to a snap feature on the pusher, the locking force between the filter elements and the retainer would need to be greater than that between the retainer and the pusher in order to disengage from the pusher.

In another embodiment of the invention the retainer is selectively movable by application of an energy stimulus from a non-retaining configuration in which the filter 1 is not retained in the closed state, to a retaining configuration in which the filter 1 is retained in the closed state.

For example, the retainer may comprise a cure adhesive. The retainer may be selectively movable by application of ultraviolet light from the non-retaining configuration in which the filter 1 is not retained in the closed state, to the retaining configuration in which the filter 1 is retained in the closed state.

For example, the retainer may comprise a biostable polymer. The retainer may be selectively movable by application of heat or an electric current to cure the polymer from the non-retaining state in which the filter 1 is not retained in the closed state, to the retaining state in which the filter 1 is retained in the closed state.

For example the retainer may comprise a biostable polymer. The retainer may be selectively movable by application of heat or an electric current to transform a non restraining polymer arrangement in which the filter 1 is not retained in the closed state, into a restraining polymer arrangement through melt flow in which the filter 1 is retained in the closed state.

For example, the retainer may comprise a two-part epoxy system. The retainer may be selectively movable by addition of the second part from the non-retaining state in which the filter 1 is not retained in the closed state, to the retaining state in which the filter 1 is retained in the closed state.

For example, the retainer may be selectively movable by application of a magnetic field from the non-retaining configuration in which the filter 1 is not retained in the closed state, to the retaining configuration in which the filter 1 is retained in the closed state.

It is appreciated that the secondary retainers disclosed above can be manufactured using a biodegradable or a biostable material to extend the protection period temporarily or permanently. If a biodegradable secondary holder is selected, it is possible to perform an additional intervention to extend the protection period further.

It will be appreciated that more than one retainer may be employed to extend the period of time in which the filter 1 captures thrombus. For example in the case where a first retainer is biodegradable and/or bioabsorbable, a second retainer may be employed to further extend the period of time in which the filter 1 captures thrombus beyond biodegrading/bioabsorbing of the first retainer. Any of the retainers may be of any suitable form as described herein. The first retainer may be of the same type or of a different type of retainer as the second retainer.

The retaining members used to extend the protection period may also be used with multistage filters. Consider a double convertible cone filter with a coarse proximal filter and a fine distal filter that separates clot particles by size where smaller particles travel through the coarse proximal filter and are trapped by the fine distal filter. The fine distal filter is intended to capture smaller particles that would normally be clinically insignificant but would present a risk to a patient with poor pulmonary reserve. After the patient has recovered to the extent that pulmonary reserve is improved but pulmonary embolism is still a risk, it would be desirable to extend the protection period only for the coarse

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proximal filter. The coarse filter is less likely to become blocked with smaller clinically insignificant particles. Having the coarse filter proximal

It is appreciated that the filter embodiments discussed above can be used for general embolic protection in any blood vessel.

It will also be appreciated that the invention is not limited to use with vena cava filters. The invention may also be employed to replace one or more bioresorbable materials in other vascular devices, such as a stent, with one or more biostable components.

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

The invention claimed is:

1. A method for treating a blood vessel, the method comprising:

locating a vascular filter in the blood vessel, the vascular filter comprising at least one filter element and a biodegradable holder directly coupled to the vascular filter at a first location, for retaining the filter in a closed state, the closed state having a restricted central channel by the at least one filter element, the filter being movable after a predetermined period of time from the closed state for capturing thrombus passing through the blood vessel to an open state having an unrestricted open central channel through the filter facilitating blood flow once the biodegradable holder degrades in the blood vessel, and

further retaining the filter, within the blood vessel, in the closed state beyond elapse of the predetermined period of time by delivering a retainer to the filter, such that it is directly coupled to the filter at the first location, the holder and the retainer both being coupled to the filter at an overlapping period of time.

2. A method as claimed in claim 1, wherein the retainer is delivered to the filter after the filter has been located in the blood vessel.

3. A method as claimed in claim 1, wherein the retainer is delivered to the filter using a delivery mechanism, and the method comprises the step of centering the delivery mechanism in the blood vessel.

4. A method as claimed in claim 1, wherein the method comprises the step of grasping the filter before delivering the retainer.

5. A method as claimed in claim 1, wherein the retainer is a clamp tube, tubular mesh, coil, or support ring.

6. A method as claimed in claim 1, wherein the filter remains in the blood vessel after the retainer is delivered.

7. A method as claimed in claim 1, further including, after delivering the retainer, removing the retainer, while the filter remains in the blood vessel, to convert the filter from the closed state to the open state.

8. A method for treating a blood vessel, the method comprising:

determining a location of a vascular filter that has been positioned in the blood vessel, the vascular filter comprising at least one filter element and a biodegradable holder directly coupled to the vascular filter at a first location, for retaining the filter in a closed state, the closed state having a restricted central channel by the at least one filter element, the filter being movable after a predetermined period of time from the closed state for capturing thrombus passing through the blood vessel to an open state having an open central channel through the filter facilitating blood flow once the biodegradable holder degrades in the blood vessel, and

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modifying the vascular filter that has been positioned in the blood vessel by further retaining the filter in the closed state, within the blood vessel, beyond elapse of the predetermined period of time by delivering a retainer to the filter, such that it is directly coupled to the filter at the first location,

the holder and the retainer both being coupled to the filter at an overlapping period of time.

9. A method as claimed in claim 8, wherein the method comprises the step of moving the retainer relative to the filter.

10. A method as claimed in claim 8, wherein the retainer is manipulated from a non-retaining state to a retaining state using an energy stimulus.

11. A method for treating a blood vessel, the method comprising:

locating a vascular filter in the blood vessel, the vascular filter comprising at least one filter element and a biodegradable holder directly coupled to the vascular filter at a first location, for retaining the filter in a closed state, the closed state having a restricted central channel by the at least one filter element, the filter being

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movable after a predetermined period of time from the closed state for capturing thrombus passing through the blood vessel to an open state having an unrestricted open central channel through the filter facilitating blood flow once the biodegradable holder degrades in the blood vessel, and

after implantation of the filter and before degradation of the biodegradable holder, modifying the filter to further retain the filter in the closed state beyond elapse of the predetermined period of time by delivering a retainer to the filter, such that it is directly coupled to the filter at the first location, wherein the filter remains in the blood vessel and continues to filter blood after modification with the retainer.

12. A method as claimed in claim 11, wherein the retainer is delivered to the filter using a delivery mechanism, and the method comprises the step of centering the delivery mechanism in the blood vessel.

13. A method as claimed in claim 11, wherein the retainer is a clamp tube, tubular mesh, coil, or support ring.

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